IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; JEANNE WALLACE individually as surviving spouse of Joseph Wallace, deceased, AND as Personal Representative of the ESTATE OF JOSEPH WALLACE; JAMES WALLACE; and SAMUEL WALLACE; EDDIE VIERS, individually as surviving spouse of Teresa Viers, deceased, AND as Personal Representative of the ESTATE OF TERESA VIERS Plaintiffs, vs. UNIVERSITY OF IOWA HOSPITALS AND CLINICS, an Iowa Entity; ADEMOLA ABIOSE; COLUMBIA UNIVERSITY MEDICAL CENTER, a New York Entity; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL, an Illinois entity; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE, a Texas entity; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL, an Ohio entity; ROBERT HOPKIN; UNIVERSITY OF MINNESOTA, a Minnesota entity; MICHAEL MAUER; DUKE UNIVERSITY HEALTH CENTER, a North Carolina entity; MANESH PATEL; UNIVERSITY OF WASHINGTON MEDICINE, a Washington entity; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL, a Massachusetts entity; KATHERINE SIMS; UNIVERSITY OF ALABAMA AT BIRMINGHAM MEDICINE, an Alabama entity; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER, a California entity; WILLIAM WILCOX; UNIVERSITY OF VERSAILLES, a French entity; AND DOMINIQUE GERMAIN Defendants.	Civil Action No. 2:22-cv-00752-CB Class Action Judge Cathy Bissoon *Electronically Filed*

FIRST AMENDED COMPLAINT

AND NOW comes the Plaintiffs, by and through their counsel, C. Allen Black, Esquire, and hereby file this Complaint as follows.

1. D.J. ("Plaintiff D.J.") is a male minor with Fabry disease, represented by and through guardians Chastity Johnson, who currently resides in Wise, Virginia and is a citizen of Virginia. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, hypohidrosis, and debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. [1,] The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is

[1] "[I]f an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible. (FN)15" *U.S. v Rutherford,* 442 U.S. 544, 556 (1979) [FN13].

now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking low dose Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.[2] His data has been reported to the database by his physician.

2. Plaintiff Toni Cordova is an adult individual with Fabry disease who currently resides in Reno, Nevada and is a citizen of Nevada. She had not been diagnosed with Fabry until the shortage began in 2009. Relying on the expert recommendations of the Defendants, she was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2011 to 2012. She had never received a full dose of the drug until the Fabrazyme shortage was over. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in her clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, stroke, transischemic attacks presenting as strokes,

[2] By registering the study with the National Institutes of Health, all researchers and sponsors agree to follow the "Common Rule" for protection of human research subjects established by the Federal Government.

white matter deposition in the brain (inflammatory foci), neuropathic pain, chronic debilitating fatigue, and chronic gastrointestinal distress including uncontrollable diarrhea. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and she is now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject received the Defendants' co-authored letters at her home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Her data has been reported to the database by his physician.

3. Plaintiff John Cortina is an adult individual with Fabry disease was a resident and citizen of Brewster, New York at the time of receiving contaminated and low-dose Fabrazyme, but now is a citizen of North Carolina. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose"

Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, acroparesthesias, and cardiovascular hypertension. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

4. Plaintiff George Demko is an adult individual with Fabry disease who currently resides in Pittsburgh, Pennsylvania, and is a citizen of Pennsylvania. Plaintiff was on treatment

with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, neuropathic pain, memory loss, arterial blockage, and chronic debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database

by his physician.

5. Plaintiff Mary Helton is an adult individual with Fabry disease who currently resides in Charlestown, Indiana and is a citizen of Indiana. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, she was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in her clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, transischemic attacks presenting as stroke, intracranial hypertension, optic nerve swelling, vision loss, hearing loss, neuropathic pain, multiple Fabry Crises, cardiac arrhythmia, chronic debilitating fatigue, and progression of kidney disease. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and she is now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to

administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at her home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Her data has been reported to the database by his physician.

6. Plaintiff Donovan Helton is an adult individual with Fabry disease who currently resides in Clinton, Indiana. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, heart arrhythmia, chronic debilitating fatigue, heat intolerance, transischemic attacks, proteinuria, multiple Fabry crises, and neuropathic pain. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants'

expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742 and received the Defendants' co-authored letters at his home residence via Federal Express. His data has been reported to the database by his physician. Plaintiff was a minor at the time of the shortage requiring special ethical considerations for informed consent.

7. Plaintiff Sydney Johnson, also known as Sydney Holmes-Dowdy is an adult with Fabry disease who currently resides in Wise, Virginia and is a citizen of Virginia. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. She was delivered and injected with "low-dose" Fabrazyme from 2009 to 2012. Plaintiff's clinical status has deteriorated as the Fabry disease has accelerated due to the "low dose" Fabrazyme treatment as evidenced by the occurrence, progression, and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, hypohidrosis, and debilitating fatigue. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and she is

now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at her home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Her data has been reported to the database by his physician. Sydney Johnson was a minor at the time of filing her complaint requiring special ethical considerations for informed consent.

8. Plaintiff Damon LaForce is an adult individual with Fabry disease who currently resides in San Pedro, California and is a citizen of California. While a resident and citizen of Virginia, Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme requiring extensive pre-medication that he did not require prior to receiving the "low dose" of drug, vascular globotriaosylceramide deposition, debilitating fatigue,

neuropathy, anaphylactic infusion reactions, and acroparesthesias. "low dose" also caused antibody sensitization to Fabrazyme making it impossible for him to resume full dose treatment with Fabrazyme without requiring steroids as he had before the "low dosing" began. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

9. Plaintiff Michael Masula is an adult individual with Fabry disease who currently resides in Pittsburgh, Pennsylvania and is a citizen of Pennsylvania. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and

dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, transischemic attacks presenting as stroke, neuropathic pain, acroparesthesias, dental erosion and loss of teeth, and chronic gastrointestinal distress including uncontrollable diarrhea. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

10. Plaintiff James Matthews is an adult individual with Fabry disease who currently resides in Indian Trail, North Carolina and is a citizen of North Carolina. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, end-stage renal disease (stage V) requiring dialysis, kidney transplant, complications of the first kidney transplant leading to dialysis and currently requiring a second kidney transplant, heat intolerance; neuropathy, fatigue, and anhidrosis. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended

and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

11. Plaintiff Thomas Olszewski is an adult individual with Fabry who currently resides in Grayling, Michigan and is a citizen of Michigan. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, chronic obstructive pulmonary disease, heart surgery, multiple heart catheterizations, neuropathic pain, acroparesthesias, and chronic debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he

reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

12. Plaintiff Tom Stanziano is an adult individual who currently resides in Oldsmar, Florida, and is a citizen of Florida. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, anaphylactic infusion reactions, acroparesthesias, hearing loss, depression, insomnia, and progression of renal disease. "low dose" also caused antibody sensitization to Fabrazyme making it impossible for him to resume full dose treatment with Fabrazyme without steroids as he had before the "low dosing" began. His disease has increased due to his reasonable reliance

on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

13. Plaintiff Eddie Viers is an adult individual who currently resides in Grundy, Virginia and is a resident of Virginia and was the spouse of Teresa Viers. Eddie Viers is the Administrator of the Estate of Teresa Viers, who was on treatment with FDA-approved doses of Fabrazyme prior to June 2009, and died due to the effects of "low-dose" Fabrazyme delivered and administered from 2009 to 2012, as evidenced by: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, recurrent febrile illness, chronic debilitating fatigue, exercise intolerance, heat intolerance, neuropathic pain, recurrent kidney infections, anaphylactic infusion reaction, increased hemoglobin count, increased creatinine,

progression of kidney disease, proteinuria, and enlargement of the heart that all contributed to her death in September of 2019. Plaintiff's life expectancy was shortened due to taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject with the clinical outcome of death and received the Defendants' co-authored letters at her home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Her data has been reported to the database by his physician.

14. Plaintiff Jeanne Wallace is an adult individual who currently resides in Richmond, Virginia and is a Virginia citizen and was the spouse of Joseph Wallace. Jeanne Wallace is the executor of the Estate of Joseph Wallace, who was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease had increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, and acroparesthesias that all contributed to his death in 2016. His disease had increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment.

Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. His life expectancy was shortened due to taking "low dose" Fabrazyme. He was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject with the clinical outcome of death and received the Defendants' co-authored letters at his home residence via Federal Express. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. His data has been reported to the database by his physician.

15. Plaintiff James Wallace is an adult individual that resides in Nashville, Tennessee and is a Tennessee citizen and is a surviving son of Joseph Wallace.

16. Plaintiff Samuel Wallace is an adult individual who currently resides in Richmond, Virginia, and is a Virginia citizen and is a surviving son of Joseph Wallace.

17. Defendant University of Iowa Hospitals and Clinics, an entity Defendant, is an Iowa corporation with a principal place of business at 200 Hawkins Drive, Iowa City, IA 52242. It receives federal funding.

18. Defendant Ademola Abiose, M.D., a physician Defendant, resides in Cleveland Ohio and is a citizen of Ohio. He was a citizen of Iowa from 2009 to 2011 and was employed at the University of Iowa Hospitals and Clinics

19. Defendant Columbia University Medical Center, an entity Defendant, is a New York corporation with a principal place of business at 630 West 168th Street, New York, New York 10032. It receives federal funding.

20. Defendant Maryam Banikazemi, M.D., a physician Defendant, is a citizen of New York and was a citizen of New York from 2009 to 2012. She was an employee of Columbia University Medical Center between 2009 and 2012.

21. Defendant Children's Memorial Hospital (n/k/a Ann & Robert H. Lurie Children's Hospital of Chicago), an entity Defendant, is an Illinois corporation with a principal place of business at 225 E. Chicago Ave., Chicago, IL 60611. It receives federal funding

22. Defendant Joel Charrow, M.D., a physician Defendant, is a citizen of Illinois. He has been an employee of Children's Memorial Hospital from at least 2009 to the present.

23. Defendant Baylor College of Medicine, an entity Defendant, is a Texas corporation with a principal place of business at One Baylor Plaza, Houston, TX 77030.

24. Defendant Christine Eng, M.D., a physician Defendant, is a citizen of Texas. She had been an employee of Baylor College of Medicine since at least 2009.

25. Defendant Cincinnati Children's Hospital Medical Center, an entity Defendant, is an Ohio corporation with a principal place of business of 3333 Burnet Ave., Cincinnati, OH, 45229. It receives federal funding.

26. Defendant Robert Hopkin, M.D., a physician Defendant, is a citizen of Ohio. He has been an employee of Cincinnati Children's Hospital since at least 2009.

27. Defendant University of Minnesota Medical Center, an entity Defendant, is a Minnesota Corporation with a principal place of business at 500 Harvard St. SE, Minneapolis,

MN, 55455. It receives federal funding.

28. Defendant Michael Mauer, M.D., physician Defendant, is a citizen of Minnesota. He has been an employee of the University of Minnesota Medical Center since at least 2009.

29. Defendant Duke University Health System, an entity Defendant, is a North Carolina Corporation with a principal place of business at 2301 Erwin Road, Durham, NC 27710. It receives federal funding.

30. Defendant Manesh Patel, M.D., a physician Defendant, is a citizen of North Carolina and has been an employee of Duke University Health System since 2009.

31. Defendant University of Washington Medicine, an entity Defendant, is a Washington corporation with a principal place of business at 325 9th Ave., Seattle, WA 98104. It receives federal funding.

32. Defendant Ronald Scott, M.D., a physician Defendant, is a citizen of Washington. He has been an employee of the University of Washington Medicine since at least 2009.

33. Defendant Massachusetts General Hospital, an entity Defendant, is a Massachusetts corporation with a principal place of business at 55 Fruit St., Boston, MA 02114. It receives federal funding.

34. Defendant Katherine Sims, M.D., a physician Defendant, is a citizen of Massachusetts. She has been employed by Massachusetts General Hospital since at least 2009.

35. Defendant University of Alabama at Birmingham Medicine, and entity Defendant, is an Alabama corporation with a principal place of business of 550 22nd St. South,

Birmingham, AL 35223. It receives federal funding.

36. Defendant David Warnock, M.D., a physician Defendant, is a citizen of Alabama. Defendant David Warnock has been an employee of University of Alabama at Birmingham Medicine since at least 2009.

37. Defendant Cedars-Sinai Medical Center, an entity Defendant, is a California corporation with a principal place of business at 8700 Beverley Blvd. Los Angeles, CA 90048. It receives federal funding.

38. Defendant William Wilcox, M.D., Ph.D., a physician Defendant, was a citizen of California from 2009 to 2012. He was employed at Cedars-Sinai Medical Center between 2009-2012.

39. Defendant University of Versailles, an entity Defendant, is a French corporation with a principal place of business of 2 avenue de la source de la Bievre, Montigny, Ile-de-France, France – 78180. The University of Versailles.

40. Defendant Dominique Germain, M.D., Ph.D., a physician Defendant, is a citizen of France and was a citizen of France. He is employed by the University of Versailles and entered the United States to attend the Fabry Stakeholders' Working Group in Chicago, IL, on June 27, 2009.

JURISDICTION AND VENUE

41. Counts I-VII: Federal jurisdiction is conferred under federal subject matter jurisdiction 28 U.S.C. § 1331 and state law related claims under 28 U.S.C. § 1343; and diversity

jurisdiction is also conferred pursuant to 28 U.S.C. § 1332 (a) as defendants and plaintiffs are all from different states and over the Class (as hereinafter defined) pursuant to 28 U.S.C. §§ 1332(d) (2) and (6) of the Class Action Fairness Act of 2005, because one or more members of the Class are citizens of a State different from the Defendant, and the aggregate amount in controversy exceeds two billion one hundred and fifteen million dollars ($2,115,000,000), exclusive of interest and costs; and for

42. Count VIII in the addition or alternative to additional Defendants acting as authorized arms of the State, Federal Jurisdiction is conferred under Original Jurisdiction for violation of the Interstate Compact Clause under the U.S. Constitution (Art. I, § 3, Clause 3). Three of the Defendants are State entities engaged in a compact to interfere with the State of Pennsylvania's police powers under the 10th Amendment to protect the health and safety of its citizens as well as the Federal power to regulate the commerce of interstate marketing of misbranded drugs under the Food, Drug and Cosmetics Acts. 21 U.S. Code § 352 (f) - Misbranded drugs and devices, as well as research the effects of such misbranded drugs on Pennsylvanians. To the extent the Defendants' authorized agents acted within the scope of their authority, they created a prima facie Interstate Compact with encroaching on the sovereign powers of the Union and the Individual States without the consent of Congress. The case can properly and immediately be forwarded to the U.S. Supreme Court.

43. Furthermore, two Plaintiffs are citizens of Pittsburgh Pennsylvania, so as to permit the Western District of Pennsylvania to exercise personal jurisdiction, and they are duly allowed to assert the State interest of Pennsylvania in violation of the Interstate Compact Clause.

44. Venue is proper because two Plaintiffs, Michael Masula and George Demko, reside in the Western District of Pennsylvania.

PROCEDURAL BACKGROUND

Some of the facts in this Complaint relate back to factual information in the co-pending product liability action filed by Plaintiffs pending in Massachusetts against Sanofi Genzyme, a pharmaceutical manufacturer. *Wilkins v. Genzyme Corp*., No. CV 21-10023-DPW, 2022 WL 4237528 (D. Mass. Sept. 14, 2022), dismissed with prejudice to certain claims and dismissed without prejudice to others (Appeal Filed, 1st Cir., October 17, 2022). No discovery has occurred.

Some facts also relate to another product liability action for wrongful death in Utah. The facts of the Utah case were not known to the Plaintiffs. Specifically, on May 21, 2020, the District Court of Utah granted STAT News' request to unseal Plaintiff's (proposed) Fourth Amended Complaint in the case *Schubert v. Genzyme* (Case 2:12-cv-00587-HCN-DAO) Exhibit A, Dkt. Nos. 173 and 207. The evidence that was unsealed revealed that "low dosing" Fabry patients with Fabrazyme was both ineffective and dangerous and that Fabry patients would not be allowed to take full dose Fabrazyme even if deterioration was observed on low dose. These specific documents are reference *infra* by the Bates numbered documents that were unsealed (*e.g*., GENZYME [00000]).

Additional facts have been developed herein that show that non-Sanofi Genzyme physicians and state actors have been involved in manipulating data to avoid disclosure of "low dose" effects on American Fabry patients despite recording these data on the Plaintiffs and other

American Fabry patients leading to the filing of the current Complaint. The Defendants are not manufacturers or sellers of a drug, but rather professionals engaged in the business of providing information of critical importance to the health and safety of individuals.

FACTUAL BACKGROUND

Fabry Disease

45. Fabry (pronounced "fah-bray") disease is a rare but lethal heritable genetic illness that occurs in approximately 1 in 3,000 births.

46. Without treatment, the disease results in the premature death of Fabry patients from complications such as renal disease, cardiac disease, and disease of the central nervous system.

47. In Fabry disease, the gene for an enzyme (alpha-galactosidase) required to metabolize a certain fat (globotriaosylceramide, termed "GL-3) is mutated or missing resulting in the buildup of GL-3 in cells, blood vessels, and organs, which causes inflammation and ultimately leads to death, usually from strokes, kidney failure, and/or heart enlargement.

48. While no cure for Fabry disease is yet available, one of the greatest breakthroughs in scientific research on Fabry disease has been enzyme replacement therapy where a synthetic version of the enzyme, Fabrazyme (agalsidase beta), can be infused intravenously every two weeks to effectively treat Fabry patients.

49. Fabrazyme does not reverse damage from Fabry disease but can mitigate the effects of toxic GL-3 production.

50. Fabrazyme infusions temporarily compensate for the absent or mutated agalsidase enzyme by clearing GL-3 buildup from the system.

51. Fabrazyme is rapidly metabolized, so it must be administered every two weeks.

52. In April of 2003, the United State Food and Drug Administration ("FDA") granted rapid orphan drug approval for Sanofi Genzyme Corporation to exclusively market and sell Fabrazyme for the treatment of Fabry patients throughout the United States.

53. Fabrazyme was developed under a federal research grant, so Sanofi Genzyme did not own the patent to Fabrazyme but rather licensed it.

54. The scientific research for the discovery of Fabrazyme was a direct result of U.S. taxpayer funding.

55. Specifically, the NIH awarded grant no. DK 34045 to Dr. Robert J. Desnick ("Desnick") at the Mount Sinai School of Medicine to develop Fabrazyme as an enzyme replacement therapy to treat Fabry Disease and conduct clinical trials at the Mount Sinai School of Medicine.

56. Mount Sinai was granted U.S. Patent No. 5,356,804 for a method of producing agalsidase beta subject to the requirements and obligations of 35 U.S.C. §§ 200-212, commonly known as the Bayh-Dole Act. Mount Sinai licensed U.S. Patent No. 5,356,804 to manufacture agalsidase beta (Fabrazyme) to Sanofi Genzyme Corporation, which has been the sole FDA-approved supplier enzyme replacement therapy to the U.S. marketplace.

57. Under the Bayh-Dole Act, the U.S. government retained certain rights to the Fabrazyme invention (U.S. Patent No. 5,356,804) to protect the public while Mount School of Medicine owned the title.

58. Fabrazyme was also granted orphan drug status, so Sanofi Genzyme (previously Genzyme Corporation) had a drug monopoly in the United States. Orphan Drug Act, 21 U.S.C.

§ 360aa *et seq*. "Protection for drugs for rare diseases or conditions"

59. Fabrazyme is the only FDA-approved drug for treating Fabry disease in the U.S., although a competitor drug (Replagal) is available in Europe.

60. From 2009 to 2012, Replagal was available through FDA's "Compassionate Use" expanded access program.

61. Currently, Fabrazyme treatment generally costs over $600,000 per year per patient, and there are over 2,000 Americans diagnosed with the disease.

Fabrazyme Shortage

62. Fabrazyme is produced in bioreactors that are similar to fermentation tanks.

63. Genetically engineered Chinese hamster ovary cells ("CHO cells") secrete the human agalsidase enzyme into the cell growth medium where it is collected and purified into an injectable form.

64. Sometime before June 2009, Sanofi Genzyme Corporation contaminated its bioreactors with Vesivirus 2117 (Allston), a genus of calicivirus.[3]

65. In mid-June 2009, Sanofi Genzyme suspended production of Fabrazyme and several other enzyme replacement drugs manufactured at its plant due to the viral contamination in the bioreactors.

66. In mid-November 2009, Sanofi Genzyme shut the plant down again due to ongoing manufacturing deficiencies.

[3] Qui Y., et al. "Identification and quantitation of Vesivirus 2117 particles in bioreactor fluids from infected Chinese hamster ovary cell cultures." *Biotechnol Bioeng.* 2013 May;110(5):13042.

67. As a consequence, Sanofi Genzyme did not have enough drug to ensure a continued supply to all of its customers both in the United States and overseas.

68. Sanofi Genzyme was also worried about competition overseas, where Replagal was available, unlike in the United States.

69. By 2008, knowing that supplies of Fabrazyme were tenuous, Sanofi Genzyme had conducted work on a Fabrazyme Global Contingency Plan and outlined a proposed response to a supply interruption in a document ("Contingency Plan"). GENZYME638592 (*Schubert*).

70. In the Contingency Plan, Sanofi Genzyme acknowledged that Fabrazyme was "very vulnerable" to manufacturing supply interruptions. The Contingency Plan detailed how Sanofi Genzyme intended to respond to a Fabrazyme supply disruption. *Id*.

71. The Contingency Plan further stated that, in the event of a supply interruption, "strong messaging" would be needed to influence physicians and patients to follow Sanofi Genzyme's suggested allocation plan during the period of shortage. *Id*.

72. Sanofi Genzyme's Contingency Plan states that in the event of a supply interruption, during the initial stages of any interruption, the **"EU markets" would be "protected" with favored treatment** because of what the authors termed the **"business value"** of the European market. *Id.*

73. Under the Contingency Plan, patients in Europe would not, at the outset, be asked to make the same sacrifices in altering their treatment regimen as would U.S. patients. *Id.*

74. In other words, Sanofi Genzyme's 2008 Contingency Plan revealed its deliberate intent to give preferential treatment to European patients in the event of a supply interruption.

75. Sanofi Genzyme planned to give "protection" to the European market during the

initial stages of a shortage because Sanofi Genzyme knew that patients in Europe could easily switch to Replagal® while patients in the U.S. could not.

Reduced Dosage of Fabrazyme[4]

76. In 2009, limited stocks of Fabrazyme were available for supply, all of which were contaminated, so Sanofi Genzyme Corporation recommended a new and untested method of treating Fabrazyme patients with what Sanofi Genzyme called "low dose" Fabrazyme or "dose skipping."

77. "Low dosing" Fabrazyme consisted of Sanofi Genzyme selling a "full dose" in the sense it was the proper mass and number of vials per weight of the patient, but "low dose" in that it was shipped once every 1-6 months instead of bi-weekly as prescribed.[5]

78. Patients were given a choice of taking a reduced dose (0.5-0.2mg/kg) every two weeks or taking a full dose (1mg/kg) administered every month or longer by skipping doses. They were not given the option to take a full dose

79. Either way, the FDA only approved Fabrazyme to be infused intravenously at 1mg/kg every other week, administered as described on the label and prescribed by the Plaintiffs' physicians.

[4] For the purpose of the complaint, a "dose" refers to the mass amount of Fabrazyme administered to a patient in one infusion (e.g., 70mg to a 150lb patient), but "dosage" refers to the amount given the patient over time 1mg/kg every two weeks. The pharmacology of Fabrazyme dosage changes whether the correct amount is given according to the patient's weight (1mg/kg) as well as according to how often the drug is administered (every two weeks).

"Low dose" means both dose-skipping and reducing the dose below 1mg/kg or a combination of the two.

80. The pretext of selling low dose to preserve the health of the U.S. Fabry Community was simply untruthful.

81. Low dose Fabrazyme does not treat Fabry disease because it is ineffective below an approved dose of 1mg/kg administered every two week.

82. Physicians skilled in the mitigation of a drug shortage always practice triage not rationing.

83. Low dose Fabrazyme is ineffective, therefore low-dose has no medical use whatsoever during whether there is a shortage or not.

Dose Reduction Recommendations of Fabry Stakeholders Working Group I (FSWG I)

June 2009 meeting (first letter)

84. To implement "low dosing," Sanofi Genzyme convened a group of experts and lay people to implement " low dosing."

85. The organization was termed "The Fabry Stakeholder's Working Group," abbreviated "FSWG."

86. The Fabry Stakeholder's Working Group comprised the physician Defendants who were representing their respective medical institutions according to the FSWG documents.[6]

[6] The signatories include Defendants Dr. Ademola Abiose (University of Iowa Hospitals); Dr. Maryam Banikazemi (Columbia University Medical Center); Dr. Joel Charrow (Children's Memorial Hospital); Dr. Christine Eng (Baylor College of Medicine); Dr. Robert Hopkin (Cincinnati Children's Hospital Medical Center; Dr. Michael Mauer (University of Minnesota); Dr. Manesh Patel (Duke University Health Center); Dr. Ronald Scott (University of Washington); Dr. Katherine Sims (Massachusetts General Hospital); Dr. David Warnock, (University. of Alabama at Birmingham Medicine); Dr. William Wilcox (Cedars-Sinai Medical Center) and Dr. Dominque Germain (University. of Versailles), all of which received payments from Sanofi Genzyme.

87. The Fabry Stakeholder's Working Group met twice.

88. The first meeting was held on June 7, 2009, in Chicago, which resulted in a document termed "**Guidance to the Fabry Community on the Management Fabrazyme (agalsidase beta) Supply**. *Temporary Conservation of the Fabrazyme Supply to Minimize the Impact of the Shortage on the Health of Patients*" that was sent to all Fabry patients in the U.S. including all of the named Plaintiffs that have Fabry disease. Exhibit A.

89. The letter states "All patients should reduce their Fabrazyme intake by the equivalent of two doses [50%] during the time period from July 1 to September 30, 2009.

90. The letter further states that "This reduction can be achieved" by "two missed infusions" or "four infusions at 0.5 mg/kg, i.e., one-half standard dose." *Id*. at 2.

91. The express stated purpose of the FSWG was to "minimize the risks" to patients and "minimize the impact" of the shortage for all Fabry patients. *Id.* at 1.

92. This first letter implemented a treatment regimen for patients outside of the territories that the physician-Defendants were licensed to practice. As such, adjusting the dosing concomitantly with sending the letters was a criminal unauthorized practice of medicine in both the State of Pennsylvania and the other Plaintiff's jurisdictions.

93. None of the co-authors of the FSWG letters sought to obtain an extraterritorial license in Pennsylvania even though the authors intended and succeed in causing both the letters and the low doses to enter the State of Pennsylvania.

94. In addition, the letters also advertised and promoted an off-label use of Fabrazyme (low-dosing) which constitutes criminal marketing of a misbranded drug in violation

of the Federal Food, Drug and Cosmetics Act and Pennsylvania's Pure Food and Drug Law as well as those of the other States.

95. The Defendants intended to directly contact both treating physicians and their patients as evidenced by the titles of both papers "Guidance for the Fabry Community" not "Guidance for Treating Physicians."

96. The intent to directly contact patients and physicians is evidenced by the inclusion of lay people in both meetings to ostensibly communicate to regular patients that their voices were being heard in the meetings. These lay people have Fabry disease, but they have no training in medicine or scientific research.

97. The intent to directly contact patients is explicitly stated as one of the goals of the guidance which includes "wide dissemination" of the guidance. *Id.* at p. 1.

98. The intent to contact patients as well as physicians is evidenced by the group command to patients. "All patients [not 'all of the physician's patients'] should reduce their Fabrazyme intake by the equivalent of two doses." *Id.* at p.1.

99. When the letter was sent out, the physician defendants all knew the letters had been sent to the Fabry disease plaintiffs because they began fielding questions in their own personal medical practices from their patients who received the letters.

Dose Reduction Recommendations of Fabry Stakeholders Working Group

June 2009 meeting (second letter)

(FSWG II)

100. The second meeting was held on September 23, 2009, where all the same individuals attended, except Dr. Dominique Germain, a French citizen.

101. In a continuing course of conduct, a second meeting was held that resulted in a document termed "**Revised Guidance to the Fabry Community on the Management of Fabrazyme (agalsidase beta) Supply**. *Temporary Conservation of Fabrazyme Supply for 2009*" that was also sent to all Fabry patients in the U.S. including the named Plaintiffs. Exhibit B.

102. The letter speaks directly to patients stating "Patients [not doctors] are encouraged to speak with their physicians about their treatment regimen."

103. On the cover page of both FSWG documents, it is noted that "individuals or their institutions or organizations receive or have received funding from Sanofi Genzyme."; however, no specific information is revealed as to any particular physician Defendant or entity Defendant that received these funds. This information was not present on the first letter. *See* Exhibits A and B.

104. In the second FSWG letter in September 2009, the dose reduction was further decreased to one-third, even including a dose reduction table for doctors and patients to follow.

105. The letters couched the recommendations as voluntary, stating that the decisions were ultimately up to the treating physician

106. However, the "voluntariness" of receiving low was illusory in that low dose would ship if the patients failed to opt-out.

107. Thus the FSWG changed the presumption of honoring state authorized

prescriptions for full dose Fabrazyme from being the default standard merely one illusory option.

108. Opting out of low dose was illusory because no one has ever reported being able to opt-out of receiving low dose or how to do it, except by begging Genzyme.

109. The unsealed document in Schubert details such begging for treatment for full doses.[1] See *Schubert v. Genzyme* (Case 2:12-cv-00587-HCN-DAO) Unsealed Exhibit A. Dkt. No. 173

110. ¶ 251. On December 3, 2009, Sarah Iden, a [Genzyme] medical affairs liaison, spoke with [decedent] Dr. Schubert about the extension of the 0.3 mg/kg dose. Dr. Schubert told Sarah Iden about his continued physical decline on the reduced dose. *Id.*

111. ¶ 252. On that same day, Keith Butler reported that Dr. Longo was "not happy with the latest FZ delay" because Dr. Longo "has two patients," one of whom was Dr. Schubert, "that are not doing well at reduced doses." GENZYME036093…. *Id.*

112. ¶ 253. Genzyme again affirmatively denied Dr. Longo's request without providing a medical reason why. *Id.* (Dr. Schubert died in the hospital without receiving a full dose of Fabrazyme).

113. None of the Plaintiffs' doctors had ever prescribed low dose Fabrazyme in the first place.

114. All of the Plaintiffs would have opted out of low dose had they known it was ineffective for treating Fabry disease.

115. More importantly, the defendants affirmatively knew that Genzyme had "adopted" the FSWG presumption of shipping low doses, even though the patients' prescriptions

did not change.

116. A forced reduction in dosage detailed in the FSWG letters is the opposite of voluntary treatment with low dose.

117. The Defendants knew that the dose reductions were mandatory because Sanofi Genzyme had already adopted the FSWG recommended dose reductions when shipping Fabrazyme irrespective of the prior physician-patient treatment decision as evidenced in the letters informing patients that their Fabrazyme dose had been reduced by the agreement made among the FSWG members.

118. The FSWG reversed the presumption of validity of prescription doses of Fabrazyme, so that Plaintiffs received low dose even thought they had a prescription for full dose.

119. The physician Defendants adopted an astonishing nine simultaneous conflicts of interest in creating the FSWG to switch Plaintiffs to low dose Fabrazyme as set forth in Paragraphs 119- 127 below .

120. First, the physician Defendants were practicing medicine against the best interest of individual patients by recommending a specific treatment for their Fabry disease. This is an archetypal doctor-patient fiduciary role owing an individualized duty to act in patients' best interests despite being unauthorized to practice medicine in the Plaintiffs' States. All Fabry patient Plaintiffs allege the FSWG members breached the duty of care under this theory. The harms from receiving low dose Fabrazyme result from this breach.

121. Second, the physician Defendants were acting as rescuers for U.S. patients with

Fabry disease that faced a drug shortage thereby owing them a duty of care to protect them as announced in the FSWG letters. Clinical treatment is an attempted rescue a person from a disease. One who interferes with a rescue attempt, or a interferes with the chattel being used in a rescue attempt commits a tort to the third party being rescued. All Fabry patient Plaintiffs allege the FSWG members breached the duty of care under this theory. The harms from receiving low dose Fabrazyme result from this breach.

122. Third, the physician Defendants were acting as public health authorities regulating the health and safety of all Fabry disease Americans for the benefit of both patients and the States as medical officers licensed to practice medicine in their own states. All Fabry patient plaintiffs allege the FSWG members breached the duty of care under this theory and in asserting the rights of their individual States to exercise police power over the public health and welfare under the 10th Amendment. The harms from receiving low dose Fabrazyme result from this breach.

123. Fourth, the physician Defendants were acting in a research-subject fiduciary role by forcing unconsented Americans to take part in an experimental drug study with the expectation that treating physicians would forward the data to them through the Fabry Registry. The Fabry disease Plaintiffs all took part in the experiment. Only the Defendant members who have access to the Fabry Registry can use and interpret the data on low dose effects. All Fabry patient Plaintiffs allege the FSWG members breached the duty of care under this theory. The harms from receiving low dose Fabrazyme result from this breach.

124. Fifth, the physician Defendants were acting on behalf of their employers who regulate the conduct of conflicts of interest for employee physicians. All Fabry patient Plaintiffs

allege the FSWG members breached the duty of care under this theory and vicarious liability theory. (Notable exceptions apply to the Univ. of Iowa, the Univ. of Alabama at Birmingham, and the University of Iowa, discussed in the Count VIII below.)

125. Sixth, the physician Defendants were acting as on behalf of the Fabry Registry database which itself required a duty of care to protect the research subjects.

126. Seventh, the physician defendants are in the professional business of supplying accurate information critical for the care and survival of patients with Fabry disease, so it is foreseeable that the information they provide will be used and relied upon by third parties. This happened to the physician defendants, because as soon as the FSWG letters arrived at their patients' home addresses, their own patients contacted them about how to opt out of low dose. The FSWG letters contain no information about the risks of low dosing—information that ethical medical professionals would normally provide. The only information on the effects of low dose in the FSWG letter citation to a clinical study that was at best inconclusive as to the effects of low dose Fabrazyme while failing to cite to the more clinically relevant Vedder study showing low dose is ineffective. The fact that FSWG member physicians even allowed their name to be attached to such a deceptive and inaccurate letter independent of who drafted it, is evidence of the complete disregard for human health and safety which they were sworn to protect. The harms from receiving low dose Fabrazyme result from this breach.

127. Eighth, the physician Defendants were assisting Genzyme in its criminal marketing campaign to defraud insurers and patients into paying for off-label low dose Fabrazyme. All Fabry patient Plaintiffs allege the FSWG members breached the duty of care under this theory. The harms from receiving low dose Fabrazyme result from this breach.

128. Ninth, the physician Defendants were acting on their own behalf since they were being paid by Genzyme in addition to being paid by their own employers.

129. After these FSWG meetings, the physician defendants and the entity defendants all observed deterioration of their own patients on low-dose but did nothing to alert anyone.

130. The "temporary" dose reduction mandate lasted an additional two and one-half years until the spring of 2012.

131. The FSWG did not meet again, although all the physician Defendants treated their own Fabry patients during the shortage by administering "low doses" to them and collected data on the effects of the "low dose."

The FSWG as a criminal conspiracy designed to violate criminal laws designed to protect consumers from injury and fraud

132. Using a drug in a manner not stated in the vial is considered "off-label" use of a drug. Such uses are not prohibited if it was prescribed by a physician, which is not the case here.

133. Marketing and promotion of a drug for an off- label use constitute misbranding of the drug in all 50 States and at the federal level misbranding a legend drug carries severe criminal and civil penalties.

134. The reason for off-label marketing and promotion is usually to defraud insurers who will not pay for a drug that is used in a manner inconsistent with the label, as is the case with selling low dose Fabrazyme.

135. Using "low dose" Fabrazyme to treat Fabry disease inconsistent with its label because it is supposed to be administered at 1mg/kg every two weeks.

136. The FDA has never granted approval for using low dose Fabrazyme.

137. Low dose Fabrazyme is ineffective as well as being off-label.

138. The FSWG was specifically created to sell low dose Fabrazyme in contravention to FDA approval.

139. The FSWG solicited and implemented a "low dose" program for all American patients unless they opted out.

140. The FSWG letters contain evidence the criminal intent of the members of the group to defraud consumers and their insurers because it affirmatively requires all U.S. Fabry patients to take low-dose Fabrazyme despite having held and continuing to hold a valid prescription for full doses.

141. The FSWG enterprise itself caused low-dosing, not the plaintiffs or their physicians.

142. Indeed, the FSWG marketing strategies of (a) sending low dose unless opting out and (b) promoting off-label use to combat the shortage while citing studies that it would be an effective treatment, and (c) de facto not allowing opt-out despite saying it was possible, caused over 95% of the U.S. Fabrazyme market to be converted from on-label to off-label use.

143. The FSWG conspiracy and marketing campaign has been the most efficient and successful off-label promotion campaign in U.S. history.

144. The FSWG conspiracy and marketing campaign also involved collecting data on the victims that continues to this day to observed what two of the FSWG members term "residual

effects."

145. The members of the FSWG have agreed that any individual member would not publish these data without authorization from the other members of the FSWG conspiracy.

146. The Centers for Medicare and Medicaid Services advises physicians to be wary of unscrupulous pharmaceutical companies attempting to engage in off-label marketing by stating "Knowing some of the forms that off-label promotion can take will make it easier to recognize this unlawful practice. The forms [of off label marketing] take paying physicians:"

A) "To pretend to be the authors…. about off-label uses when the articles were actually written by manufacturers' agents" (The Defendants are either pretending to be authors of the FSWG documents or they are actual authors where the Defendants authorized the FSWG letters to go out under their names with professional titles are appended);

B) To serve as members of "advisory boards" promoting off-label use; (All Defendants were members of the FSWG advisory board);

C) To travel… to listen to promotions about off-label use; (Genzyme paid for the members of the FSWG to travel to FSWG advisory board meetings);

D) To give promotional lectures [or material] in favor of off-label use to fellow practitioners (The Defendants intended the FSWG letters to reach physicians in states in which the Defendants are not authorized to practice medicine);

and,

E) Publicizing studies showing efficacy of off-label uses while suppressing studies showing no efficacy…. (Only Lubanda study is cited but not the more relevant

Vedder study, which found that low dose was not efficacious in treating Fabry disease. Each of the Defendants signed their name to this deceptive act.)

CMS monograph, "Off-Label Pharmaceutical Marketing: How to Recognize & Report It," (2015).[7]

147. The targeting of physicians with off-label information about non-approved use is termed "detailing" physicians.

148. The First Circuit explains "detailing" with regard to the fraudulent marketing for the ineffective drug Neurontin: "This fraudulent marketing included, but was not limited to, three strategies, each of which included subcomponents: (1) direct marketing (or 'detailing') to doctors, which misrepresented Neurontin's effectiveness for off-label indications… and (3) suppressing negative information about Neurontin while publishing articles in medical journals that reported positive information about Neurontin's off-label effectiveness." In re Neurontin Mktg. & Sales Pracs. Litig., 712 F.3d 21, 28 (1st Cir. 2013).

149. The fraudulent marketing misrepresenting "detailing" other physicians about the effectiveness of low dose Fabrazyme by citing only to the Lubanda instead of the Vedder study mirrors the Neurontin fraudulent marketing, with the vitiating fact that off-label low dose had already being mandated to treat all U.S. Fabry disease patients.

Unethical Research on "Low Dose" Patients by the Defendants Post-Marketing

[7] Available at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf

150. In the second FSWG letter to U.S. Fabry patients, the physician Defendants also encouraged all U.S. doctors and patients to document the effects of "low dosing" in a U.S. database termed "The Fabry Registry." This research objective forcing low-dose was not present in the first FSWG letter. Exhibit A and B.

151. Most U.S. Fabry patients, including the Plaintiffs, are registry research subjects.

152. The Fabry Registry is ostensibly an "observational" longitudinal study for collecting data on Fabry disease and treatment where "[n]o experimental intervention is involved," even though the FSWG changed the protocol so that all U.S. research subjects were mandated to receive an experimental "low dose" of Fabrazyme in lieu of the prescribed dose. (NIH ClinicalTrials.gov Identifier: NCT00196742).[8]

153. Unlike the original use of the Fabry Registry, the FSWG stated in 2009 that it specifically wanted to collect data on U.S. patients being "low dosed" "[B]ecause there is limited published data on the clinical effects of dose reductions or treatment interruptions, the collective data from many patients may provide valuable answers to these important unanswered questions through future analyses." Exhibit B, p.5.

154. Unilaterally lowering the dose of Fabrazyme while collecting data on the unknown effects is substantive human experimentation despite the description of the Fabry Registry being observational because patients were opted into taking low dose without consent.

155. Under 21 CFR § 312.3 (b), treating Fabry with "low dose" Fabrazyme is considered an investigational use for a new drug because the drug is only known to be efficacious

[8] Available at https://clinicaltrials.gov/ct2/show/NCT00196742

at 1mg/kg every other week. "The FDA has long held that when an investigator limits his choices, his patient's choices and the choices of the people working for him in the treatment of those patients, then he is conducting a clinical investigation. That is different from the practice of medicine, where the primary intent is to treat the individual patients not the community. (*emphasis added*) Center for Drug Evaluation and Research, FDA, "Warning Letter to Hennepin County Medical Center" June 2021).[9] *See also* FDA's guidance to industry Investigational New Drug Applications (INDs)- Determining Whether Human Research Studies Can Be Conducted Without an IND (published in September 2013), at 4, 15 ("For example, a randomized trial evaluating an unapproved use of a lawfully marketed drug is a clinical investigation and may require an IND).

156. None of the Plaintiffs were under the treatment or care of Defendants, so the Defendants had no personal knowledge of the Plaintiffs' particular risks and likely adverse effects that "low dose" would have on them other than through the data the Defendants have collected on them through the Fabry Registry.

157. The Defendants did not obtain informed consent from any of the U.S. patients to be to agree to take low dose.

158. The FSWG requirement that Fabry Registry patients be changed protocol from an observational status to an experimental status for monitoring the clinical effects of the unapproved dosages of Fabrazyme was not put before an Institutional Review Board.

159. Both FSWG letters explicitly state "that patients in clinical trials [such as the

[9] Available at https://www.hennepinhealthcare.org/wp-content/uploads/2021/10/FDA-Warning-Letter-and-Hennepin-Healthcare-response-letter-Hospital-MayJune-2021.pdf

Fabry Registry] should adhere to the study protocol" which is to taking the physician-prescribed dose of Fabrazyme. Ex. A and Ex. B

160. There could not be any yearly follow-up as required under the Common Rule promulgated in response to the Belmont Report for the protection of human research subjects.[10]

161. The Defendants did not obtain informed consent from patients because they did not tell research subjects what the effects of "low dose" Fabrazyme were likely to be.

162. The Defendants did not obtain informed consent from patients because they did tell the research subjects that the emerging data in the Fabry Registry likely showed that "low dose" was ineffective and dangerous.

163. The Defendants also did not obtain informed consent because American Fabry patients were never able to voluntarily opt out of "low dose" by presenting full-dose prescription and return to the FDA approved dose of Fabrazyme that was (and remains) the gold standard of medical care for treating Fabry disease in the U.S. thereby removing any patient autonomy and the ability to determine their own medical care.

164. The Defendants did obtain informed consent because the FSWG did not disclose that American Fabry patients would be treated unequally. The Europeans could obtain and did obtain a full dose of Fabrazyme during the shortage.

165. The Defendants also did not obtain informed consent even within the United States because some high prestige Americans were given full doses, but the unequal treatment was not disclosed to any of the other Fabry registry patients.

[10] *See,* for example the Office of Human Research Protection and the Common Rule available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

166. The Defendants also did not obtain informed consent because the FSWG members limited disclosing their conflicts of interests to an ambiguous aggregate, stating that "some" of them had received money from Sanofi Genzyme, when in actuality "most" of them, if not all, had been paid by Sanofi Genzyme.

167. The Defendants did not obtain informed consent because the FSWG members only cited to the Lubanda study that was equivocal and not the more clinically relevant Vedder study discussed *infra* that showed "low dose" was ineffective. [11,12]

168. The Defendants acted unlawfully because they did not attempt to warn patients that the "low doses" were likely ineffective and dangerous once this data became evident either through the registry or through observation of the effects of "low dose" on their own patients as is required during any use of an investigational new drug whether an Investigational New Drug application has been submitted.

169. The FSWG was also coercive as well as being deceptive.

170. It acted in unison to "persuade" Americans to take "low doses, "without discussing whether individually discussing the decision in private with individual Fabry patients. The group of doctors making the recommendation was viewed by the Plaintiffs as more persuasive than if the members published their opinions separately.

171. It did not include a contact number for an Institutional Review Board but instead

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[11] **Vedder** AC, Breunig F, Donker-Koopman WE, Mills K, Young E, Winchester B, Ten Berge IJ, Groener JE, Aerts JM, Wanner C, Hollak CE: Treatment of Fabry disease withdifferent dosing regimens of agalsidase: effects on antibody formation and GL-3. Mol Gen Metab. 2008

[12] **Lubanda** JC, Anijalg E, Bzdúch V, Thurberg BL, Bénichou B, Tylki-Szymanska A. Evaluation of a low dose, after a standard therapeutic dose, of agalsidase beta during enzyme replacement therapy in patients with Fabry disease. Genet Med2009;11(4):256

directed individuals to the manufacturer of the drug.

172. The members of the FSWG used guilt and shame to encourage compliance. By describing the shortage as affecting everyone, the implicit understanding was that not being a team player would result in injury to other innocent victims or shaming within the Fabry community. This threat is especially magnified because Fabry patients are often related to each other and treated by the same physician. If one family member found out another was receiving a full dose, acrimony and retaliation would result.

173. The FSWG was also coercive and deceptive because the implicit understanding was that if a patient did not take the "low dose, " they would get nothing. In other words, "something was better than nothing."

174. If the "low dose" was rejected, then dissenters would be punished by not receiving anything, while the compliant group would at least get something.

175. The Defendant Institutions all require informed consent for all research studies conducted by employees and actively monitor their employees for breaches of the "Common Rule" protecting human research subjects no matter the source of funding.

176. The research conducted by the Defendants was on a taxpayer-funded patented drug in which the U.S. government held rights and responsibilities toward U.S. Fabry patients.

177. The Defendant institutions are required to investigate and report research misconduct to the U.S. Office of Research Integrity, which they have not done.

178. The Defendants are aware of the ethical and legal responsibilities for conducting human clinical trials since they have conducted and continue to conduct human research and have received federal funding to conduct clinical trials on humans with other conditions.

Plaintiffs' Discovery That "Low Dosing" is Useless and Dangerous

179. The perception among the Plaintiffs has been that "something was still better than nothing" when using "low dose" Fabrazyme, which is what the FSWG wanted individuals to believe.

180. However, The Plaintiffs discovered that something was not better than nothing by May 21, 2020.

181. On this date, the court in Utah unsealed a complaint that held evidence that Sanofi Genzyme knew the "low dose" was ineffective in treating Fabry Disease. *Schubert v. Genzyme* (Case 2:12-cv-00587-HCN-DAO).

182. On March 12, 2012, Dr. Schubert's widow sued Sanofi Genzyme corporation and other entities for the wrongful death of her husband, who suffered from Fabry.

183. Dr. Schubert was quickly deteriorating on "low dose" Fabrazyme and begged Sanofi Genzyme to give him full doses, but Sanofi Genzyme refused, and Dr. Schubert died of complications from Fabry disease on March 6, 2010.

184. The *Schubert* case settled for an undisclosed amount.

185. Sanofi Genzyme's Global Medical Director, Dr. Daniel Gruskin, who attended both FSWG meetings, colorfully characterized the Lubanda data on which the efficacy of "low dose" was predicated. On January 18, 2011, in an email to his colleague, Andre Richer, Dr. Gruskin said that "We totally screwed the pooch and PV [pharmacovigilance] is to blame, although we let them do it. We sent the EMA [European Medical Association] bullshit data [on "low dose"] and then are surprised when they come up with recommendations to switch to

Replagal®." GENZYME511440 (*Schubert*).

186. This same "bullshit data" was presented to the physicians attending the Fabry Stakeholder's Working Group, who reviewed it and subsequently forwarded it under their names to treating physicians and their patients.

187. Specifically, before the shortage, there were only two peer-reviewed and published patient studies studying the effect of Fabrazyme treatment at doses lower than the full FDA-approved dose. One article's principal author was Vedder, and the other's was Lubanda.

188. The Vedder study, which was published in 2007, was the only study evaluating the clinical outcomes of patients on reduced doses. The Vedder study revealed that a lower dose of Fabrazyme (0.2 mg/kg administered every other week) was not clinically efficacious for a large number of subjects enrolled in the study and that "no reduction in left ventricular mass or other disease parameters" was observed after nearly two years of treatment on the reduced dose. The Vedder study also showed that when study subjects who deteriorated on the reduced dose were switched back to the full FDA-approved dose later, it failed to stop "further progression of the disease."

189. On the other hand, the Lubanda study (cited in the second FSWG letter absent the Vedder study), published in 2009, only evaluated the effect of a lower dosage of Fabrazyme (0.3 mg/kg every 2 weeks) on measurable biomarkers that can be evaluated by lab testing of subjects. The study found that some patients taking the reduced dose had a change in biomarker levels, and some did not. Ex. B.

190. Of critical import, the studied biomarker had not then, and still has not, been proven to be correlated with clinical outcomes. In other words, there is no proof that Fabrazyme

in such "low doses" forestalls or delays the progression of cardiac or other disease processes caused by the enzyme deficiency in Fabry Disease patients.

191. Additionally, the authors of the Lubanda study expressly stated in the published study paper that "the small sample size together with the short duration of this exploratory study did not permit analyses of clinical outcomes."

192. To encourage adoption of "low dose," Sanofi Genzyme touted the Lubanda study, while downplaying the more clinically relevant Vedder study, while simultaneously lying about the projected duration of the shortage.

193. Sanofi Genzyme admitted lying at the FSWG meetings.

194. Dr. Gruskin, then Sanofi Genzyme's Global Medical Director, who had attended both FSWG meetings, sent an email to another Sanofi Genzyme employee who attended the meeting, asking, "Did we lie to the fswg?" The email response from his colleague, John King, Marketing Director of Fabrazyme, stated, "We are the only ones who didn't" lie. GENZYME047527 (*Schubert*).

195. In October 2009, and while Sanofi Genzyme was implementing and communicating its plan to supply all U.S. patients with "low dose" Fabrazyme without disclosing any medical risks for patients taking the reduced dose, Sanofi Genzyme was actively marketing against Australian governmental approval of a similarly reduced dose of Fabrazyme. Sanofi Genzyme warned the Australian medical authority of grave dangers to patients if the reduced dose was approved for clinical use.

196. From July to October 2009, the Australian medical regulatory authority was evaluating whether it could reduce the approved dose of Fabrazyme to 0.2 mg/kg every two

weeks as the FSWG regulatory body had done to save its citizens 80% of the enormous cost of treatment of Fabrazyme.

197. The Australian medical authority asked Sanofi Genzyme to respond as to whether it was medically safe for patients to order Fabrazyme in a reduced dose.

198. In responding to Australia's recommendation that Fabrazyme be approved at a dose of 0.2 mg/kg administered every two weeks, Sanofi Genzyme's senior management, including many of the same Sanofi Genzyme management involved in reviewing, approving, and communicating the "low-dose" plan for U.S. Fabry patients to accept a reduced dose.

199. Sanofi Genzyme's response to Australian medical authorities warned that reducing the dose "to 0.2 mg/kg . . . across the board would have significant clinical consequences for patients, with the expectation that many would suffer irreversible harm as a result of insufficient dosing," and that "treatment at a higher dose is necessary and may be life-saving." In the same communication, Sanofi Genzyme stated that the suggestion to "reduce the dose of Fabrazyme® to 0.2 mg/kg in all patients ignores the cumulative evidence in the extant literature" and that to believe such a reduction could occur "with little or no loss of efficacy is conjectural." GENZYME013854; GENZYME013847 (*Schubert*).

200. In the same response letter, Sanofi Genzyme officials cited the Vedder study and its conclusion that a dose of 0.2 mg/kg of Fabrazyme® was "suboptimal" and would not "elicit[] a clinically relevant response to treatment." *Id.*

201. In a related email, Sanofi Genzyme senior management stated that such a "**blanket dose adjustment would be insane.**" GENZYME013840 (*Schubert*).

Specific Knowledge of Defendants

202. The Defendants knew the Fabry Registry data proved that "low dose" Fabrazyme was ineffective and dangerous.

203. Despite Sanofi Genzyme lying to the Defendants, the Defendants still undertook a duty to independently monitor the effects of the "low dose" plan they had implemented and had the means and expertise to monitor the effects through the Fabry Registry.

204. The Defendants specifically stated that the data the Defendants recorded on "low dose" patients would be valuable because there was little data showing that it was efficacious or safe. Exhibit B, p. 5.

205. The Defendants affirmatively stepped outside their role as individual treating physicians to assume responsibility for managing the entire U.S. Fabrazyme supply by creating the autonomous FSWG and representing themselves individually "as internationally-recognized physicians with deep clinical and scientific expertise" from well-respected institutions who would "minimize the risk for patients." Exhibit A, p.2.

206. Management of the national drug supply to protect citizens during a shortage is the customary government role of state and federal public health authorities.

207. The FSWG recommendations were not "recommendations" but rather a mandate with the force of law so that American patients could not receive full doses and could not appeal the decision to accept "low doses" to any governmental body.

208. The Defendants knew the "low dose" would be made (and had been made) mandatory, thereby defeating any doctor-patient autonomy that existed before the FSWG. Plaintiffs could only beg Sanofi Genzyme as Dr. Schubert had done to provide the standard of

care their doctors prescribed.

209. The Defendants acted outside of the doctor-patient relationship by making community recommendations because "practice of medicine" is limited to acting in the best interest of an individual patient but the practice of public health is directed to the community.

210. When the FSWG appointed themselves authorities to manage the allocation of the Fabrazyme supply in all 50 U.S. states without taking into account individual medical conditions, they were not acting as governmental public health officers.

211. The FSWG did not even act competently as a public health authority. Triage is the standard of care during a shortage, not rationing.

212. For example, most males are likely to die of Fabry disease by 50, whereas females can live to an average age, so males are therefore more likely to die without full dose treatment.

213. The vast majority of U.S. Fabry patients were not under the medical care of any of the Defendant physicians when they mandated that American Fabry patients take the lower dose while collecting data on them without informed consent or the ability to opt-out of the experimental treatment, so they were completely dependent on the FSWG and its members.

214. The Plaintiffs and all American Fabry patients reasonably relied on the FSWG physicians to "minimize the risk to patients" and would not have taken "low dose" Fabrazyme had they known that "blanket dose adjustment **would be insane**" and that the "low dose" protocol was based on "bullshit data."

215. The ongoing concealment of the registry data on "low dose" treatment made it impossible to discover these material facts of their injuries or the cause of their injuries because the Plaintiffs do not have access to the Fabry Registry or the expertise necessary to analyze the

results.

216. The reason that a reasonable person would be "**insane**" to take a lowered dose is that the medical data on "low dose" is "bullshit," as confirmed by the data that was collected on over 1,500 American Fabry patients for two and one-half years.

217. The physician Defendants have always been able to access the Fabry Registry data at their convenience when they encouraged the collection of data on patients receiving "low dose." Physician Defendants have personally accessed these data and continue to access these data to this day and have a duty to report the effects of low dose.

218. Indeed, between 2009 and at least 2012, all physician Defendants also served on the North American Board of Advisors for the Fabry Registry separately from the Fabry Stakeholders Working Group. Defendant Dominique Germain served on the International Fabry Registry during this period.

219. In 2011, Defendant Dr. David Warnock (Chair) stated in the Foreword to the Fabry Registry Annual Report that "we would like to recognize the many challenges that Fabry physicians and their patients have faced during the past year due to the interruption in the manufacturing of agalsidase beta. Amidst this difficulty, we would like to thank all of the participating sites who have reported their patients' changes in treatment status and other clinical data during this difficult period."

220. Defendant Dr. Warnock, who chaired the Registry Board, further states that "It is essential that the Fabry Registry collects these data to better understand clinical impact of these treatment changes for patients."

221. Neither Defendant Dr. Warnock nor the other Fabry Stakeholder Working Group

physicians have reported this "essential" data and have systematically acted to conceal these data from the Fabry research subjects.

222. The Defendants have not reported this data because it proves the "low dose" of Fabrazyme is ineffective and dangerous compared to the full dose.

223. The Defendants could have disclaimed their recommendation for dose reduction at any point in the two and one-half years of the shortage. Still, after reviewing the data in the Registry the Defendants they did not want to incriminate themselves in the injury of thousands of innocent Americans and the fraudulent billing of hundreds of millions of dollars for "low dose" Fabrazyme to Medicare, Medicaid, Veterans Affairs, and private insurers, none of which pay for experimental, non-FDA dosages of medication.

224. Defendants could have told U.S. Fabry patients that the use of Replagal would have been a better alternative than low-dose Fabrazyme since it had been clinically evaluated and approved for use by many governments' medical regulatory agencies while "low-dose" Fabrazyme had not.[13]

225. Remarkably, when the European physicians eventually published data on a

[13] Expanded access (also termed "Compassionate Use") may be appropriate when all the following apply:
1) Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
2) There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
3) Patient enrollment in a clinical trial is not possible.
4) Potential patient benefit justifies the potential risks of treatment.
5) Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.
(Investigational New Drug Application, Subpart I–Expanded Access to Investigational Drugs for Treatment Use. (Food and Drugs, 21 C.F.R. §312.300–312.320 (2009))

handful of overseas patients that chose to remain on "low dose," Defendants Dr. Warnock and Dr. Mauer published an article summarizing these European results. It was entitled *Fabry Disease: Dose Matters* but omits discussing the U.S. data they had collected over the years on thousands of Americans who had received "low dose." (**Warnock** DG, **Mauer** M. "Fabry disease: dose matters" J Am Soc Nephrol. 2014 Apr;25(4):653-5. *Available at* https://jasn.asnjournals.org/content/25/4/653.long)

226. Instead of discussing the data they held on U.S. Fabry patients, the authors bizarrely ask "What lessons were learned from the 2.5 year shortage of agalsidase beta?" The authors rhetorically reply that "Studies… which took advantage of an unfortunate and quite prolonged drug shortage are important." *Id*. This muted statement is far from his pronouncement as chair of the Fabry Registry that "It is essential that the Fabry Registry collects these data…." *Emphasis added*.

227. Defendants Dr. Warnock and Dr. Mauer also failed to note that the U.S. Fabry Registry contains data on 1,510 U.S. patients as of 2010 who received "low dose" Fabrazyme, as opposed to the handful of Europeans that received "low doses" and who were the subject of the article.

228. Over 10 percent of the Registry subjects were children in 2010 who required special considerations instead of being aggregated with adult Fabry patients to receive "low doses."

229. The adverse effects of "low dose" are most detrimental to children because as

children grow, they need significantly more Fabrazyme as their body mass increases.[14] ("Start of treatment with effective doses of enzyme replacement before age 16, in male Fabry Disease patients is associated with reduced occurrence of renal and cardiac manifestations of Fabry Disease, as assessed by intermediate endpoints.") *Id.* and Tøndel C, *et al.* (concluding that "long-term enzyme replacement therapy in young patients can result in complete globotriaocylceramide clearance of mesangial and glomerular endothelial cells across all dosage regimens, and clearance of podocyte inclusions is dose-dependent." *Emphasis added*.)[15]

230. Plaintiffs D.J., Sydney Johnson, an Donovan Helton were all minors during the shortage and experienced growth over the 2 and one half that the dose was being reduced.

231. Many adult Fabry patients who had milder symptoms offered their doses to their children so they would not be injured, but Genzyme refused to make the adjustment, as was in the case of Plaintiff D.J.'s mother trying to help her son. The blanket dose adjustment recommended by the FSWG did not take children's rapid growth into account, when the members knew or should have know increasing the dose over time would be critical for the health and safety of these children.

232. Similarly, as published by the Defendants, males are the most likely to benefit from an early start to an effective full dose of Fabrazyme, and, by inference, the most likely to

[14] van der Veen SJ et al. *Early start of enzyme replacement therapy in pediatric male patients with classical Fabry disease is associated with attenuated disease progression*. Mol Genet Metab. 2022 Feb;135(2):163-169. doi: 10.1016/j.ymgme.2021.12.004. Epub 2021 Dec 17

[15] Tøndel C, *et al. Agalsidase benefits renal histology in young patients with Fabry disease.* J Am Soc Nephrol. 2013 Jan;24(1):137-48

suffer from "low doses."[16,17,18, 19,]

233. Even more disturbing, Defendants Dr. Warnock and Dr. Mauer also warned that "low dose" patients, including the children, are at risk for "residual effects" from "low dose" that have never been disclosed.

234. One residual effect is that the "low dose" sensitizes the immune system by creating antibodies so that a patient will not be able to tolerate a return to full dose without medical intervention such as steroid pre-treatment.

235. Another effect is that the "low dose" actually accelerated the course of Fabry disease in some patients as reported by the European Medicines Association, the European equivalent to the FDA. European Medicines Agency Report Assessment Report "Assessment report on the shortage of Fabrazyme" (Nov. 2010).[20]

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[16] **Hopkin RJ**, Cabrera G, **Charrow J**, Lemay R, Martins AM, **Mauer M**, Ortiz A, **Patel MR**, **Sims K**, Waldek S, **Warnock DG**, **Wilcox WR**. *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry*. Mol Genet Metab. 2016 Sep;119(1-2):151-9. doi: 10.1016/j.ymgme.2016.06.007. Epub 2016 Jun 13.

[17] Ortiz A, **Abiose A**, Bichet DG, Cabrera G, **Charrow J**, **Germain DP**, **Hopkin RJ**, Jovanovic A, Linhart A, Maruti SS, **Mauer M**, Oliveira JP, **Patel MR**, Politei J, Waldek S, Wanner C, Yoo HW, **Warnock DG**. *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. J Med Genet. 2016 Jul;53(7):495-502. doi: 10.1136/jmedgenet-2015-103486. Epub 2016 Mar 18.

[18] **Warnock DG**, Ortiz A, **Mauer M**, Linthorst GE, Oliveira JP, Serra AL, Maródi L, Mignani R, Vujkovac B, Beitner-Johnson D, Lemay R, Cole JA, Svarstad E, Waldek S, **Germain DP**, Wanner C; *Fabry Registry. Renal outcomes of agalsidase beta treatment for Fabry disease: role of proteinuria and timing of treatment initiation. Nephrol Dial Transplant.* 2012 Mar;27(3):1042-9. doi: 10.1093/ndt/gfr420. Epub 2011 Jul 29.

[19] **Germain DP**, Weidemann F, **Abiose A**, **Patel MR**, Cizmarik M, Cole JA, Beitner-Johnson D, Benistan K, Cabrera G, **Charrow J**, Kantola I, Linhart A, Nicholls K, Niemann M, **Scott CR**, **Sims K**, Waldek S, **Warnock DG**, Strotmann J; *Fabry Registry. Analysis of left ventricular mass in untreated men and in men treated with agalsidase-β: data from the Fabry Registry.* Genet Med. 2013 Dec;15(12):958-65.

[20] available at https://www.ema.europa.eu/en/documents/other/chmp-public-assessment-report-shortage-fabrazyme_en.pdf

Defendants' Ongoing Statistical Manipulations to Conceal Data That "Low Dose" is Ineffective

236. The Defendants had hoped that "low dose" Fabrazyme would be effective, but once it became apparent that U.S. Fabry patients were being injured and dying from "low dose," they became remakrably silent on the "low dose" issue, where they had previously been eager to weigh in as expert advisors.

237. Even worse, the Defendants began concealing the "low dose" data they had collected from 2009-2012 in the Fabry Registry.

238. When reporting data from the Fabry Registry after 2012, the Defendants have used methods of statistical manipulation to conceal the American "low dose" data: exclusion and averaging.

239. All the data points are relevant and necessarily reported in any scientifically sound longitudinal study, but when an intervening variable changes (such as dosage), the data is explained, not excluded. Specifically, in a standard longitudinal study, a rise in Fabry-related deaths or adverse events between 2009 and 2012 would be noted due to receiving the "low dose" instead of being excluded altogether.

240. The first paper, published in March 2016, is ambiguous about "low dose" inclusion criteria. It was entitled: *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. [21] The materials and methods section

[21] Ortiz A, **Abiose A**, Bichet DG, Cabrera G, **Charrow J**, **Germain DP**, **Hopkin RJ**, Jovanovic A, Linhart A, Maruti SS, **Mauer M**, Oliveira JP, **Patel MR**, Politei J, Waldek S, Wanner C, Yoo HW, **Warnock DG**., *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. J Med Genet. 2016 Jul;53(7):495-502. doi: 10.1136/jmedgenet-2015-103486. Epub 2016 Mar 18.

states that to be included in the analysis, the patients need to have received a dosage "at or near [*sic*] the recommended dose of 1mg/kg every two weeks." The authors do not explain what criteria constitute a "nearly" recommended dose of Fabrazyme or whether "low dose" patients' data was reported.

241. The second paper, published in June 2016 the same year, unequivocally excludes the effect of "low dose" data instead of examining the outcomes that Defendant Dr. Warnock had previously stated were essential.

242. The second paper is flawed because it artificially limits the end of the research to when "low dose" began. It was entitled: *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry*.[22] The materials and methods section states that data were only analyzed up until June 25, 2009, "when many began temporary agalsidase beta dose reductions owning to manufacturing issues."

243. By 2018, Defendants began to hint that blanket dose adjustment was not as efficacious as they had once believed. Defendants Dr. Germain, Dr. Mauer, Dr. Eng, and Dr. Hopkin stated in another review of the data on the handful of Europeans who did not switch to alternative treatment or full doses that "[i]t has become increasingly clear that comprehensive and timely treatment of adult patients with Fabry disease should be directed toward prevention

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[22] **Hopkin RJ**, Cabrera G, **Charrow J**, Lemay R, Martins AM**,** Mauer M, Ortiz A, **Patel MR**, **Sims K**, Waldek S, Warnock DG, **Wilcox WR**. *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry.* Mol Genet Metab. 2016 Sep;119(1-2):151-9. doi: 10.1016/j.ymgme.2016.06.007. Epub 2016 Jun 13.

of (further) progression to irreversible tissue damage and organ failure."[23] These Defendants further stated that "[t]he clinical heterogeneity of Fabry disease mandates an individualized approach to patient care that reflects the genotype, gender, family history, phenotype, and specific clinical symptom severity of a given patient." *Id.*

244. These researchers still danced around the core issue of whether or not "low dose" Fabrazyme was safe or effective because they knew from the U.S. Fabry Registry data that a blanket dose adjustment was "**insane**" and based on "bullshit data."

245. Sanofi Genzyme explicitly blamed the FSWG for requiring Americans to take the "low dose" while Europeans were allowed to take the full dose. In an Fabrazyme Supply Update sent only to Europeans on October 3, 2011, it said that "in the USA, where no other approved treatment for Fabry disease is currently available, the FSWG (Fabry Stakeholders Working Group) recommended that no group of [American] Fabry patients should be designated to receive full dose, as this would require a significant further reduction in dose or no treatment at all for other US patients treated with Fabrazyme."

246. By 2016, Defendants knew that one of the risk factors for severe clinical Fabry disease was "low dose" but affirmatively decided not to report it.

247. In October of 2020, the Defendants changed tactics for concealing the effects of "low dose" Fabrazyme while emphasizing the beneficial effects of receiving an FDA approved

[23] Ortiz A, **Germain DP**, Desnick RJ, Politei J, **Mauer M**, Burlina A, **Eng C, Hopkin RJ**, Laney D, Linhart A, Waldek S, Wallace E, Weidemann F, **Wilcox WR**. *Fabry disease revisited: Management and treatment recommendations for adult patients.* Mol Genet Metab. 2018 Apr;123(4):416-427. doi: 10.1016/j.ymgme.2018.02.014. Epub 2018 Feb 28. (p. 419).

dose that the on the "low dose" patients."[24]

248. Instead of excluding the patients that received "low doses" as they had before, the Defendants averaged the dose longitudinally so patients receiving "low dose" would be considered "nearly given" the recommended dosage of Fabrazyme.

249. Specifically, in a subsequent study on Fabry registry subjects, the inclusion criteria were "an average dose at or near the licensed dose of 1 mg/kg EOW [every other week] (range 0.9–1.1 mg/kg EOW)." It also states that "Registry data entered up to January 8th, 2019, w[as] analyzed," which includes the same patients that had been excluded from the prior studies.

250. Since significant time had passed since the shortage, the patients that once received "low doses" would now "nearly" receive a full dose of Fabrazyme since the dose is averaged over 10-15 years.

251. Averaging the Fabrazyme dosage when reporting data over a longitudinal study is misleading in two ways.

252. First, any adverse events observed on "low dose" are diluted over time.

253. Second, once a treatment benefit of full dose is identified, the study's statistical power is artificially magnified even though for part of the time, patients did not receive the FDA recommended dosage.

254. Consequently, the physician Defendants are continuing to actively conceal the effects of "low dose" on the Plaintiffs and all other Americans were required to take it for two

[24] **Hopkin RJ,** Feldt-Rasmussen U, **Germain DP**, Jovanovic A, Martins AM, Nicholls K, Ortiz A, Politei J, Ponce E, Varas C, Weidemann F, Yang M, **Wilcox WR**. *Improvement of gastrointestinal symptoms in a significant proportion of male patients with classic Fabry disease treated with agalsidase beta: A Fabry Registry analysis stratified by phenotype.* Mol Genet Metab Rep. 2020 Oct 30;25:100670.

and one-half years.

255. No one in the United States benefited from the mandated experimental use of "low dose" Fabrazyme.

CLASS ALLEGATIONS

256. Researching the effects of substituting an ineffective treatment for an effective treatment in a progressive disease and then monitoring the effects on patients follows a long line of infamous involuntary research cases in U.S. history. Such cases share common actors, common facts, and common injuries, so they have been handled as a class.

257. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff Masula, Plaintiffs herein, and all others similarly situated, request certification of this case for any U.S. citizen that is or was a research subject of the effects of "low dose" Fabrazyme ("the Class").

258. The requirements of Rule 23(a)(1) are satisfied. With respect to the torts of the Defendants against the Plaintiffs and the required medical monitoring, the proposed Class is so numerous that joinder of all members of the Class is impractical and the administration of the claims as set forth herein on behalf of the Class is more efficient and will benefit the parties and the Court.

259. The exact size of the Class and the identities of the individual members thereof are ascertainable through Defendants' records, including but not limited to the Fabry Registry.

260. The requirements of Rule 23(a)(2) are satisfied. With respect to the torts committed by

the Defendants and the required medical monitoring, the questions of law and fact common to the Class predominate over the questions affecting only individual members of the Class, including the following:

a. Whether reduced dose Fabrazyme is ineffective to treat Fabry disease;

b. Whether Defendants knew, or should have known, that reduced dose Fabrazyme was ineffective to treat Fabry disease;

c. Whether the reduced dose can cause an increased risk of future medical conditions, which require medical monitoring, thereby enforcing FSWG's promise to undertake a study of the effects of "low dose" Fabrazyme on Americans;

d. Whether the Class is entitled to damages as a result of Defendants' conduct, including reimbursement for the costs of contaminated Fabrazyme, the costs of medical monitoring, the personal injuries suffered by recipients, conservatorship of the data unlawfully from the Plaintiffs, and punitive damages, and/or attorneys' fees and costs; and

e. Whether the Class is entitled to liquidated damages in the aggregate for the deprivation of rights valued at the cost of Fabrazyme that they should have been provided had the violation not occurred.

261. The requirements of Rule 23(a)(3) are satisfied. Plaintiff's claims as set forth herein are typical of the claims of the Class as they have all suffered similar harms, namely, financial loss, physical injury, and the need for future medical monitoring, and are based on the same legal theories related to the allegations of Defendants' actions and omissions.

262. Plaintiffs and members of the Class were all research subjects during the relevant time period.

263. The requirements of Rule 23(a)(4) are satisfied. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class because their interests

do not conflict with the interests of the individual members of the Class. Plaintiffs will fairly, adequately, and vigorously represent and protect the interests of the members of the Class and has no antagonistic interest to the members of the Class. Plaintiffs will retain competent and experienced counsel to represent herself and the members of the Class if the Class is certified.

264. The claims of Plaintiffs and the Class are substantially identical, as explained above. The aggregate damages that may be awarded to members of the Class are likely to be substantial, whereas the expense and burden of prosecuting such claims on an individual basis would be burdensome, economically infeasible, and procedurally impracticable. Certifying the Class will centralize these substantially identical claims in a single proceeding, which is the most manageable litigation method available to Plaintiffs and the Class.

WHEREFORE, Plaintiffs demand judgment against Defendant, jointly and severally, in an amount in excess of $5,000,000.00, together with costs of suit and punitive damages as applicable. JURY TRIAL DEMANDED.

COUNTS

COUNT I: TORT OF FAILURE TO OBTAIN INFORMED CONSENT

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT

HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT(to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

265. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

266. The tort of informed consent exists at common law in all states and is foundational under Constitutional federal law's right to medical autonomy. See generally, *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261 (1990) and *Id.* at 269. (This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment). *See also* 45 CFR §46.116 General Requirements for Informed Consent.[25]

[25] (a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

267. Due to the change in dose that the researchers had recommended, the researcher-subject relationship for the Plaintiffs and other Fabry Registry participants changed so substantively that a new informed consent was (and still is) required to collect further data on the subjects.

268. The physician Defendants did not disclose any risk, much less material risks, to taking low dose Fabrazyme.

269. The physician Defendants used coercive tactics, including cherry-picking research studies to present a positive result from using "low dose," and failing to inform subjects how to obtain full doses.

270. The physician Defendants also used coercive tactics by making it seem that it was "low dose" or nothing when Replagal was available as an alternative to "low dose."

271. Similarly, they appealed to the entire U.S. Fabry community (not just doctors) to accept "low doses," thus making it shameful to request a full dose even though it would be in

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(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

their best interest.

272. One risk of taking "low dose" Fabrazyme is that the Fabry vascular globotriaosylceramide deposition will increase, thereby injuring the brain, kidney, heart, and nervous system.

273. A second risk of taking "low dose" Fabrazyme is antibody sensitization to the Fabrazyme itself, resulting in anaphylaxis when patients return to full dose.

274. A third risk is the acceleration of the Fabry disease process through unknown mechanisms, as reported by the European Medicines Agency.

275. The fourth risk of taking "low dose" includes the "residual effects" disclosed by Defendants Warnock and Mauer.

276. These risks actually materialized in the Plaintiffs as evidenced by their decline in clinical status during the shortage and none return to their original health when full doses were instituted two and one-half years later.

277. Plaintiffs would not have taken "low dose" Fabrazyme had they had that low dosing was "**insane**" and based on "bullshit data."

278. The physician Defendants further breached the duty of providing informed consent to the American Fabry Registry subjects by failing to act without consideration of age or vulnerability or abide by the Plaintiffs' prescribing physician's prescription for full dose, which led to the expected injuries of males having worse clinical outcomes than similarly dosed females, although all suffered worse clinical outcomes than if they had received full doses for the two and one-half years that the "low dose" effects were studied.

279. The physician Defendants also breached the duty of providing informed

consent to the American Fabry Registry subjects by not submitting the change in protocol from being observational at 1mg/kg every other week to an experimental dose violating procedural protections against human experimentation, which would have protected the Plaintiffs from being offered a "low dose" in the first place.

280. In addition, the physician Defendants breached the duty of providing informed consent to the American Fabry Registry subjects by not providing a way for the Defendants to opt out of the experimental lose dose when their disease was increased. Thus the "low doses" were coerced by an FSWG mandate for Americans but not Europeans.

281. The physician Defendants also breached the duty of providing informed consent to the American Fabry Registry subjects by not timely reporting that adverse events were increasing in the patients that were receiving "low dose" Fabrazyme.

282. The physician Defendants further breached the duty of providing informed consent by subsequently concealing the adverse effects of low dose despite such data being "essential" to determine the medical effect of "low dose" on Fabry patients.

283. Defendant entities monitored the physician Defendants but never enforced their policies against unethical human research in addition to vicarious liability attaching under the doctrine of *respondeat superior*.

284. Moreover, the entity Defendants provide medical care to a subset of Fabry Registrants and provide data to the Fabry Registry and are thus active participants in the research being conducted without informed consent.

285. The entity Defendants have also failed to report (and continue) to fail to report the research misconduct to federal and state authorities despite being under a duty to do so.

286. Both the entity and physician Defendants breached the duty of providing informed consent to the American Fabry Registry subjects by not providing full disclosure of the monies the Defendants had received and continued to receive from Sanofi Genzyme during the human experimentation on "low dose" Fabrazyme from 2009-2012.

287. The Defendants have continued in their misconduct through overt acts of statistical manipulation of data reported in 2016 and, most recently, in October of 2020.

288. In addition to the physical injuries and having to pay hundreds of thousands of dollars for a drug that the Defendants knew was medically worthless, the Plaintiffs have also suffered the indignity of being treated as less-than other Fabry disease patients.

289. The Plaintiffs did not and could not determine that "low dose" was utterly useless without the evidence discovered from the unsealing of the *Schubert* Complaint.

290. Physician Defendants knew that U.S. patients were under the mistaken impression that "low dose" Fabrazyme was clinically valuable in that "something would be better than nothing." Still, the Defendants failed to point this out even though they had a duty to speak.

291. Entity Defendants are both directly and vicariously liable for these torts.

292. The tort has continued because each time researchers access the Fabry Registry, a new dignitary injury occurs absent obtaining a new informed consent.

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

293. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania's individual Fabry patients engaged in a state protected doctor-patient

relationship for treatment their Fabry disease.

294. Each author of the Fabry Stakeholders Working Group letters intended to and successfully effected a change in the Fabrazyme doses for Pennsylvania Plaintiffs' DEMKO and MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease Plaintiffs.

295. The letters' purpose was not to inform patients about Fabry disease, but to rather announce the mandatory Fabrazyme dose reduction encourage capture of the data on the effects of low dose in the existing Fabry Registry. As such the letters were testamentary and functional, not informational.

296. The FSWG did not ask patients, doctors, the Pennsylvania public health authorities, or the FDA for permission to reduce dose.

297. The letters were also deceptive even evidencing three of the off-label marketing practices that can are used to spot fraud against a consumer and their insurer according to the Centers for Medicare & Medicaid Services. This practice included "paid service on "expert board" (FSWG), paid travel to a pitch for off-label use (Genzyme underwriting the meeting), citing to studies showing efficacy of the off-label (citing Lubanda et al.) use while suppressing studies showing no efficacy (not citing Vedder, et al.) as well as not disclosing conflicts of interests.

298. Importantly, the FSWG intended to and succeeded in changing the dose of Plaintiffs' Fabrazyme without ever having to consult Pennsylvania physicians, her in Pennsylvania patients or the Pennsylvania Board of Medicine.

299. The letters were sent only as secondary act in violation the rights and protections of the Plaintiffs in their home state.

300. The FWG caused low dose Fabrazyme to enter the State of Pennsylvania.

301. The fact that Genzyme "drafted" and "mailed" the letters is not exculpatory but inculpatory because the physician Defendants and the drug company admit closely working together by sharing resources for targeting Pennsylvanians and the citizens of other U.S. states. Specifically, if the physicians use their expertise to pitch low doses, then Genzyme could use its knowledge of the Pennsylvania prescription rolls disclosing the treating physician/patient pairs to reach Pennsylvania patients.

302. The FSWG members were all authors of the FSWG letters, which is why the Genzyme sought physician Defendants' approval and signature before forwarding them. The scheme could not have worked without the cooperation and encouragement of the physician Defendants.

303. The FSWG letters' also content proves that the physician Defendants knew or should have known the letter were going to Pennsylvania patients and not just Pennsylvania doctors.

304. The fact that the activity was expressly targeted to Genzyme's mailing list is extraordinarily specific to each of those individuals that shared patient protected information on their disease with Genzyme

305. Plaintiffs never intended or expected to be contacted by non-treating physicians that they never had consulted.

306. Physician defendants and Genzyme were working together by their own admission to market an off-label drug in violation of federal and state law.

307. The physician Defendants absolutely knew what they were doing when attending the meeting, discussing off-label use at the meeting, and appending their name,

professional titles, to a document they helped author all the while being paid by Genzyme.

308. The fact that almost every Fabry patient in the U.S. changed dosing without FDA knowledge and consent proves exactly how effective the FSWG was in switching patients to the off-label use of Fabrazyme.

309. Moreover, each author knew or should have known that they were engaging in the unauthorized practice of medicine in Pennsylvania when they authorized sending letters these letters under their name and titles because these Defendants are in the business of providing accurate and critical information for the safety and survival of human beings with Fabry disease.

310. Pennsylvania has a unique relationship with the practice of medicine within its borders.

311. The practice of medicine in statutorily defined in Pennsylvania 63 Pa. Stat. § 422.2. **"Medicine and surgery."** The art and science of which the objectives are the cure of diseases and the preservation of the health of man.

312. The objective of recommending any use of Fabrazyme at any dose is to "preserve the health of man."

313. In Pennsylvania, "No person other than a [Pa. State Board Licensed] medical doctor shall engage in any of the following conduct except as authorized or exempted in this act: **(1)** Practice medicine and surgery" or "**3)** Hold forth as authorized to practice medicine and surgery [in Pennsylvania] through use of a title, including, but not necessarily limited to, medical doctor. 63 Pa. Stat. § 422.10 (Unauthorized practice of medicine and surgery)

314. All of the authors made treatment recommendation in the FSWG letters in contravention to § 422.10 (1) as well as holding themselves out as "M.D.s" without stating that they are not authorized to practice medicine in the State of Pennsylvania in contravention to § 422.10 (3).

315. By soliciting treatment recommendations to Pennsylvanians without having a Pennsylvania medical license, the physician Defendants are subject to criminal and civil penalties under 63 Pa. Stat. § 422.39.

316. These criminal activities were directed at the forum state of Pennsylvania and its citizens so as to constitute sufficient contacts and effects for purposes of jurisdiction.

317. The purpose of the Defendants using Genzyme to mail the criminal solicitations was to exploit Genzyme's customer list and thereby influence the medical treatment and care of Pennsylvania citizens. Genzyme merely "licked the stamp."

318. The arrival of the letters at the homes of these two Pennsylvanians was not passive, attenuated or fortuitous, but for the express purpose of changing how Fabrazyme is both prescribed and used in Pennsylvania by resident doctors and patients.

319. The state of Pennsylvania relies on the objectivity of its state licensed doctor's recommendations for clinical treatment as part of its effort to deter and prevent the sale of misbranded drugs to Pennsylvanians that the FSWG actively undermined.

320. Pennsylvania specifically states that a drug shall be deemed misbranded **"**Unless its labeling bears (i) adequate directions for use, and (ii) such **adequate warnings** against use in those pathological conditions or by children where its use may be dangerous to health or against **unsafe dosage.**" 35 Pa. § 780-108 (6).

321. The physician defendants knew that the vials of Fabrazyme carry no warnings about the safety of the low-dosage or any risks from taking it at such an unsafe dosage, but the FSWG letters recommend the unapproved use anyway, resulting in misbranded drug being sent to Pennsylvania patients.

322. By soliciting Pennsylvania Fabry patients to use Fabrazyme in an off-label manner, the physician defendants were intentionally aiding Genzyme's crimes and civil fraud promoting off-label use of low-dose Fabrazyme in the Sate of Pennsylvania.

323. Pennsylvania regulates medical licenses and pharmaceutical warnings to protect the health and safety of Pennsylvanians.

324. The legislative purpose of the regulation of the practice of medicine is to ensure the safety and effectiveness of medical treatment for individual Pennsylvania residents as well as to regulate the public health for the Commonwealth.

325. By soliciting and causing experimental doses of drug to be administered to Pennsylvania without a license to practice medicine, the nexus of the state interest (regulation of practice of medicine, prohibition of sale of misbranded drugs, and regulation of medical research), the tortious conduct (deprivation of Plaintiffs DEMKO's and MASULA's right to full dose and informed consent) and the effect of harm (experimental low dose treatment was not efficacious) are properly subject to jurisdiction in the District Court of the Western District of Pennsylvania.

326. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in the amount six-hundred thousand dollars

($600,000) per U.S. Fabry Registry victim per year that they received the "low dose" for a total of two billion one hundred and fifteen million dollars ($2,115,000,000), together costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT II: BREACH OF FIDUCIARY

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

327. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

328. The physician Defendants stood and still stand in an archetypal fiduciary role of researcher-human research subject special confidence and trust resulting from a position of superiority and influence acquired by virtue of participating in the FSWG.

329. The physician Defendants also created a position of a fiduciary by causing Plaintiffs to rely on "low doses" for treatment of Fabry Disease in the United States by

recommending it in the first place even though there was no substantial evidence that it would work in lieu of full doses.

330. The physician Defendants induced this reliance by assuming an autonomous and coercive role in treating Fabry patients' disease independent of the prescribing physician's judgment to administer full doses.

331. The physician Defendants breached their fiduciary responsibility by placing the needs of the generic U.S. Fabry community above the interests and needs of individual Fabry patients.

332. The physician Defendants also breached their fiduciary responsibility of full disclosure by not telling anyone that alternative treatment, Replagal, was available through the FDA.

333. The physician Defendants breached their fiduciary responsibility by misleading the Plaintiffs into believing that "something was better than nothing."

334. The duty was further breached by concealing (and continuing to conceal) the data proving "low dose" Fabrazyme was medically useless in treating the Plaintiffs and the other research subjects in the Fabry Registry. [26]

335. The physician Defendants' fiduciary duty has not ended because they still collect data on the Plaintiffs and most other American Fabry disease patients through the Fabry Registry.

[26] The last time the Supreme Court allowed an ineffective drug to be marketed under common law in the U.S. was in 1911 for "Dr. Johnson's Mild Combination Treatment for Cancer" because the seller did not mislead about the ingredients but only misled about the effectiveness of the drug for treating cancer. President Taft subsequently encouraged Congress to tighten the Food, Drugs and Cosmetics Acts to prevent such sales of ineffective drugs from happening again and the law was changed.

336. The Defendants have continued in the misconduct through statistical manipulation of data in both 2016 and, most recently, in October of 2020.

337. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act with the honesty in addition to vicarious liability attaching under the doctrine of *respondeat superior*.

338. Moreover, the entity Defendants provide medical care to a subset of Fabry Registrants and provide data to the Fabry Registry and are thus continuing to be active participants in the research that was tortiously conducted and is still tortiously conducted on the U.S. Fabry patients.

339. The Plaintiffs did not and could not determine that "low dose" was completely useless without the evidence discovered from the unsealing of the *Schubert* Complaint.

340. Plaintiffs would not have taken "low dose" Fabrazyme had they had that low dosing was "**insane**" and based on "bullshit data" and would have stopped taking "low dose" Fabrazyme had they known.

341. Physician Defendants knew that U.S. patients were under the mistaken impression that "low dose" Fabrazyme was clinically valuable in that "something would be better than nothing," but Defendants knew otherwise and had undertaken a duty to speak as a continuing fiduciary to the patients that received "low dose" Fabrazyme.

342. The Plaintiffs continue to rely on the fiduciary responsibilities of the physician Defendants to report the adverse events, the lack of effectiveness, and the residual effects of receiving "low dose" Fabrazyme because the Plaintiffs do not have access to the data in the U.S. Fabry Registry.

343. Entity Defendants are both directly and vicariously liable for these torts.

344. The tort has continued because the research is ongoing. As such, a fiduciary must correct past misstatements and misimpressions as part of the continuation of the fiduciary relationship.

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

345. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania patients engaged in a state protected doctor-patient relationship for treatment their Fabry disease.

346. Each author of the Fabry Stakeholders Working Group FSWG letters intended to and successfully effected a change in the Fabrazyme doses for Pennsylvania Plaintiffs' DEMKO and MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease plaintiffs. The letters' purpose was not to inform patients about Fabry disease, but to rather announce the reduction of the dose of Fabrazyme being given to these patients for collecting data on the effects of the experimental dose the FSWG recommended. As such the letters were functional, not informational.

347. As such, the FSWG undertook a ongoing duty of care and honesty with the Plaintiffs.

348. The legislative purpose of the regulation of the practice of medicine is to ensure the safety and effectiveness of medical treatment for individual Pennsylvania residents as well as to regulate the public health for the Commonwealth.

349. By soliciting and causing experimental doses of drug to be administered to

Pennsylvania without a license to practice medicine, the nexus of the state interest (regulation of practice of medicine and prohibition of misbranding drug), the tortious conduct (breach of fiduciary) and the effect of harm (low dose treatment that was not efficacious) are properly subject to jurisdiction in the District Court of the Western District of Pennsylvania.

350. Plaintiffs DEMKO and MASULA were harmed by the unethical and tortious medical experiment on them while living in Pennsylvania. They did not consent to the research currently being conducted on them.

351. Nothing is unfair or unexpected about being haled into the jurisdiction where the intent was to create a relationship with Pennsylvanian research subjects who never requested or consented to be Guinea pigs in the physician defendants' research experiment.

352. The research/subject relationship in the Fabry Registry went from begin observational (non-fiduciary) to experimental (fiduciary) the moment the FSWG decided to de facto substitute non-FDA approved treatment for Fabry disease to physicians and patients in the state of Pennsylvania, unless they opted out.

353. No method of opting out was even provided by the FSWG.

354. The fact that the FSWG was successful in changing the doses of Fabrazyme for Pennsylvania residents was a direct result and, indeed, evidence of the effectiveness in targeting Pennsylvanians with FSWG actions and letters.

355. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

356. Thus, as a direct and proximate result of Defendants' conduct alleged herein,

Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT III: (42 U.S.C. § 1981) Equal Protection under the Law

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

357. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

358. Physician Defendants and entity Defendants interfered with the Plaintiffs' fundamental state and federal constitutional right to medical autonomy.

359. Plaintiffs had an individualized doctor-patient contract with their treating

physician with which the Defendants interfered.

360. The discriminatory conduct was for access to a drug in which the U.S. government held rights under the Bayh-Dole Act.

361. In addition, the experiment was conducted using Fabrazyme, which is invention funded and partially owned by the U.S. government for which all federal protections for its citizens exists and for which "misuse" and "non-use" of the invention as detailed herein are specifically of federal concern to protect U.S. individuals.

362. Defendants interfered with and countermanded U.S. Fabry Patients' right to choose the medical treatment that was individually best for them, which is especially egregious because the dosage they received was less than the government-approved FDA sanctioned dose.

363. The deprivation of the right to medical autonomy was specifically directed to a relatively small and vulnerable population that has a genetic mutation in their DNA.

364. The deprivation was aimed at two named Pennsylvanians with Fabry disease.

365. The FSWG letter were targeted mailings to Fabry Disease individuals known to be under the care of a Pennsylvania treating physician.

366. The FSWG intended to and foresaw that the mailings would be sent to patients and not just doctors because they observed patients in their own clinical practice receiving them and questioning them about why they were being low dosed without their consent.

367. The FSWG had already reduced their doses by mandate. The letter were merely testamentary of the fact.

368. The disabling of the right to medical autonomy was not equal. European Fabry patients were given full dose as the cost of further reducing the doses to this vulnerable group of

Americans.

369. Plaintiffs necessarily relied on the laws of the states and federal government to protect their right to medical autonomy.

370. "Low dose" treatment occurred at all the Defendants' facilities.

371. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

372. These violations of equal protection under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

373. These violations continue in that the data is still being collected on U.S. Fabry Registry patients without informing them or their physicians of the effects of "low dose" so that the Plaintiffs can receive necessary medical care to treat "low dose" injuries.

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

374. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania patients engaged in a state protected doctor-patient relationship for treatment their Fabry disease.

375. One of the foreseeable effects of substituting an experimental drug for standard of medical care is that the drug might not be efficacious for patients under medical care in Pennsylvania and results in harm to Pennsylvania citizens.

376. Each author of the Fabry Stakeholders Working Group FSWG letters intended to and successfully effected a change in the dose of Pennsylvania Plaintiffs' DEMKO and

MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease plaintiffs. The letters' purpose was not to inform patients about Fabry disease, but to rather inform patients that their Fabrazyme dose had been reduced and that they were being subjected to research on the effects of this experimental dose on them. As such the letter were functional, not informative.

377. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

378. The deprivation of the right to medial autonomy as a direct and proximate result of the Defendants' conduct alleged herein. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT IV: (42 U.S.C. § 1983)

Protection Of Rights from Those Acting Under Color of Law

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT

HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

379. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

380. Physician Defendants and entity Defendants interfered with the Plaintiffs' fundamental state and federal constitutional rights to medical autonomy by interfering with and countermanding U.S. Fabry Patients' right to choose the individual medical treatment best for them. These acts are especially egregious because the dosage they received was a substitute for the FDA-approved dose known to be clinically effective.

381. The physician Defendants were acting under color of law because the unilateral substitution of the experimental dosage mandated across all 50 states in response to a drug shortage is a right reserved to public health authorities. The right to control public health for the residents of the individual states is reserved to the sovereign States alone at common law and under the 10th Amendment.[27]

382. By usurping the role of public health authorities and the state-licensed physicians in treating the citizens of the 50 U.S. states, the Defendants acted both with color and force of

[27] *See Jacobson v. Massachusetts*, 197 U.S. 11 (1905) generally and at 25 "[t]he State may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety."

law to defeat the state powers to address public health concerns within their state borders. The Defendants did not have any permission or authority from governmental bodies reduce the dose of Fabrazyme, a U.S. taxpayer funded invention.

383. The physician Defendants are also state-licensed individuals who acted as state-licensed authorities and used this power to coerce and mislead the American Fabry patients who received "low dose" Fabrazyme as evidenced by the title of "Medical Doctor," which they used to sign the FSWG letters.

384. The FSWG and its members were not authorized by any state or the FDA to make substitutions for the FDA-approved doses of Fabrazyme during the shortage and were similarly prohibited from marketing or encouraging the use of such an unapproved drug under the 50 states' individual Pure Food and Drug acts and the federal Pure Food, Drug and Cosmetics Acts.

385. The deprivation of the right to medical autonomy was specifically directed to a relatively small and vulnerable population that has a genetic mutation in their DNA.

386. The deprivation was aimed at two named Pennsylvanians with Fabry disease.

387. The FSWG letter were targeted mailings to Fabry Disease individuals known to be under the care of a Pennsylvania treating physician.

388. The disabling of the right to medical autonomy was not equal. No American group except for Fabry patients have ever been forced to use an experimental dose of an FDA approved drug. Even among those with Fabry disease, the Plaintiffs were treated unequally because some American patients and most European Fabry patients were allowed to obtain FDA approved doses on Fabrazyme. The Plaintiffs doses were decreased even further so that more Fabrazyme (a U.S. taxpayer funded invention) could be shipped overseas.

389. Since Fabrazyme is an invention funded and partially owned by the U.S. government, anyone receiving it must be given equal protection under the law.

390. These equal protections are vital so as not to remove the limitations on the government-granted monopoly powers under the Bayh-Dole act and under the Orphan Drug Act. For Fabrazyme, these protections are specifically designed to protect the intended beneficiaries of American Fabry patients, who constitute a rare disease population.

391. The deprivation of the right to medical autonomy was arbitrary and capricious because the patients' clinical need for full doses was not considered.

392. Plaintiffs necessarily rely on the laws of the states and federal government to protect their right to medical autonomy.

393. "Low dose" treatment has been administered at all of Defendant facilities.

394. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

395. These violations of equal protection under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

396. These violations of equal protection continue in that the data is still being collected on U.S. Fabry Registry patients without revised consent or restitution and the treating physicians have not be informed of the injuries and risks of injury for the Plaintiffs receiving "low dose."

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

397. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania patients engaged in a state protected doctor-patient relationship for treatment their Fabry disease.

398. One of the foreseeable effects of substituting an experimental drug for standard of medical care is deterioration of the health of patients under medical care in Pennsylvania and results in harm to Pennsylvania citizens.

399. Each author of the Fabry Stakeholders Working Group FSWG letters intended to and successfully effected a change in the dose of Pennsylvania Plaintiffs' DEMKO and MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease plaintiffs. The letters' purpose was not to inform patients about Fabry disease, but to rather inform patients that their Fabrazyme dose had been reduced and that they were being subjected to research on the effects of this experimental dose on them. As such the letter were functional, not informative.

400. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

401. The deprivation of the right to medial autonomy and informed consent is a direct and proximate result of the Defendants' alleged conduct.

402. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT V: (42 U.S.C. § 1985 (3)) Conspiracy to Deprive Rights from Citizens

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

403. Physician Defendants and entity Defendants acted in concert to conspire to remove the state and federal constitutional protections to medical autonomy by interfering with and countermanding U.S. Fabry Patients' right to choose the medical treatment that was individually best for them.

404. The deprivation was aimed at two named Pennsylvanians with Fabry disease.

405. The FSWG letter were targeted mailings to Fabry Disease individuals known to be under the care of a Pennsylvania treating physician.

406. In addition, the experiment was conducted using Fabrazyme, which is invention funded and partially owned by the U.S. government for which all federal protections for its

citizens exists and for which "misuse" and "non-use" of the invention as detailed herein are specifically of federal concern to protect U.S. individuals.

407. Constitutional protections attach to patients injected with such the federally owned inventions.

408. The conduct is especially egregious because the dosage they received was less than the FDA approved dose of Fabrazyme and thus an untried and experimental dosage that had not been proven to be either safe or effective in the treatment of Fabry Disease.

409. Evidence of conspiracy exists in that the physician Defendants attended both the first and second FSWG meetings, except for Defendant Dr. Germain, who attended once.

410. All of the physician Defendants sat on the U.S. Fabry Registry Board simultaneously during the shortage, and all of the Defendants have received (and continue to receive) monies from Sanofi Genzyme

411. The Defendants still work together to publish data on their victims while concealing the effects of "low dose" from the Plaintiffs.

412. These violations of equal protection and the right to medical autonomy under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating reporting Fabry Registry data.

413. These violations also continue because the data is still being collected on U.S. Fabry Registry patients without revised informed consent or restitution.

414. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

415. "Low dose" treatment occurred at all of the entity Defendants' facilities.

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

416. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania patients engaged in a state protected doctor-patient relationship for treatment their Fabry disease.

417. One of the foreseeable effects of substituting an experimental drug for standard of medical care is deterioration of the health of patients under medical care in Pennsylvania and results in harm to Pennsylvania citizens.

418. Each author of the Fabry Stakeholders Working Group FSWG letters intended to and successfully effected a change in the dose of Pennsylvania Plaintiffs' DEMKO and MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease plaintiffs. The letters' purpose was not to inform patients about Fabry disease, but to rather inform patients that their Fabrazyme dose had been reduced and that they were being subjected to research on the effects of this experimental dose on them. As such the letter were functional, not informative.

419. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

420. The deprivation of the right to medial autonomy and informed consent is a direct and proximate result of the Defendants' alleged conduct.

421. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs

of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT VI: (42 U.S.C. § 1986) Negligent Deprivation of Rights of Citizens

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

422. Since the physician Defendants and entity Defendants acted in concert to conspire to remove the state and federal constitutional protections to medical autonomy, they were also obligated to act when they observed additional violations of protections under the law.

423. The tortious acts of the conspirators were both observed and facilitated by others.

424. In addition, the experiment was conducted using Fabrazyme, which is invention funded and partially owned by the U.S. government for which all federal protections for its

citizens exists and for which "misuse" and "non-use" of the invention as detailed herein are specifically of federal concern to protect U.S. individuals.

425. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

426. "Low dose" treatment occurred at all of entity Defendants facilities.

427. Their failure to act has resulted in the continued systematic deprivation of medical autonomy and informed consent over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

428. The research and publication of data on the victims required numerous other individuals to act at the direction of the named Defendants.

429. These violations also continue because the data is still being collected on U.S. Fabry Registry patients without revised consent or restitution.

The District Court of the Western District of Pennsylvania has specific jurisdiction over the Defendants.

430. The letters constitute successful criminal solicitations targeted specifically at Pennsylvania patients engaged in a state protected doctor-patient relationship for treatment their Fabry disease.

431. One of the foreseeable effects of substituting an experimental drug for standard of medical care is deterioration of the health of patients under medical care in Pennsylvania and results in harm to Pennsylvania citizens.

432. Each author of the Fabry Stakeholders Working Group FSWG letters intended to and successfully effected a change in the dose of Pennsylvania Plaintiffs' DEMKO and

MASULA for Fabrazyme as well as most patients in the United States including all of the Fabry disease plaintiffs. The letters' purpose was not to inform patients about Fabry disease, but to rather inform patients that their Fabrazyme dose had been reduced and that they were being subjected to research on the effects of this experimental dose on them. As such the letter were functional, not informative.

433. Foreign Plaintiffs consent to the jurisdiction of this court over Defendants regarding the count being asserted above.

434. The deprivation of the right to medial autonomy and informed consent is a direct and proximate result of the Defendants' alleged conduct.

435. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT VII: VIRGINIA WRONGFUL DEATH (Code of Virginia §8.01-50) or in the alternative SURVIVAL ACTION CLAIMS (Code of Virginia §8.01-25)

EDDIE VIERS, individually and as administrator of THE ESTATE OF TERESA VIER as substituted for Teresa Viers; JEANNE WALLACE, individually and as administrator of THE ESTATE OF JOSEPH WALLACE as substituted for Joseph Wallace; WITH JAMES WALLACE; AND WITH SAMUEL WALLACE; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v.

ADEMOLA ABIOSE (to the extent acting outside his scope of duties and unauthorized by his employer); COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER;

MANESH PATEL; RONALD SCOTT (to the extent acting outside his scope of duties and unauthorized by his employer); MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; DAVID WARNOCK (to the extent acting outside his scope of duties and unauthorized by his employer); CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

436. Eddie Viers, individually and as Administrator of the Estate of Teresa Viers, brings this action on behalf of the beneficiaries under and by virtue of the Wrongful Death Act, Code of Virginia §8.01-50, and the applicable rules of civil procedure and decisional law.

437. Jeanne Wallace, individually and as Administrator of the Estate of Joseph Wallace brings this action on behalf of the beneficiaries under and by virtue of the Wrongful Death Act Code of Virginia §8.01-50 and the applicable rules of civil procedure and decisional law.

438. As a result of the Defendants' acts and omissions, Teresa Viers and Joseph Wallace were caused grave injuries and death, resulting in the entitlement to damages to those individuals defined as beneficiaries under the Wrongful Death Act.

439. The named administrators claim all administrator's expenses recoverable under the Wrongful Death Act, including, but not limited to damages for hospital, medical, funeral, and burial expenses and all expenses of administration made necessary because of Teresa Viers' and Joseph Wallace's deaths.

440. The Wrongful Death Act beneficiaries of the Estate of Teresa Viers are Eddie Viers, spouse

441. The Wrongful Death Act beneficiaries of the Estate of Joseph Wallace are:

a. Jeanne Wallace, spouse;

b. James Wallace, son and

c. Samuel Wallace, son.

442. On behalf of wrongful death beneficiaries, the Administrators claim damage for monetary support that decedents would have provided to the beneficiaries during their lifetime, including, but not limited to the support provided or which could have been expected to have been provided to the beneficiaries.

443. On behalf of the beneficiaries, the Administrators claim damages for loss of companionship, comfort, society, guidance, solace, and protection by the decedents.

444. On behalf of the wrongful death beneficiaries, the Administrators claim damages for the full damages allowed under the Wrongful Death Act of Virginia and decisional law interpreting the Act.

445. Plaintiffs consent to jurisdiction of the Western District of Pennsylvania and rely on its jurisdiction over the Defendants as set forth above.

WHEREFORE, Plaintiffs demand damages against Defendants in an amount in excess of $50,000.00, exclusive of pre-judgment interest, post-judgment interest and costs. JURY TRIAL DEMANDED

AND IN THE ALTERNATIVE--SURVIVAL ACTION[28]

446. On behalf of the Survival Action beneficiaries under Code of Virginia § 8.01-

[28] *See Centra Health, Inc. v. Mullins* 277 Va. 59, 79 (2009) explaining that both causes of action can be brought until proximate cause is determined, but election is not required earlier.

25, the Administrators claim all loss of income, retirement, and social security income as a result of the deaths of Teresa Viers and Joseph Wallace.

447. On behalf of the Survival Act beneficiaries, the Administrator claims damages for the pain, suffering and inconvenience endured by Teresa Viers and Joseph Wallace, including, but not limited to their physical pain and suffering and mental pain and suffering.

448. Plaintiffs claim the full measure of damages under the Survival Act.

449. Plaintiffs consent to jurisdiction of the Western District of Pennsylvania and rely on its jurisdiction over the Defendants as set forth above.

WHEREFORE, Plaintiffs demand damages against Defendant in an amount in excess of $50,000.00 under the Survival Act, exclusive of prejudgment interest, post- judgment interest and costs. JURY TRIAL DEMANDED

COUNT VIII: Violation of the Interstate Compact Clause

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE (to the extent acting within his scope of duties and authorized by his State employer); UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT (to the extent acting within his scope of duties and authorized by his State employer); UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK (to the extent acting within his scope

of duties and authorized by his State employer)

Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

450. Entity Defendants University of Iowa, University of Alabama at Birmingham, and University of Washington claim to be arms of the States of Iowa, Alabama, and Washington, respectively.

451. The respective physician Defendants claim to be officers of the State of Iowa, the State of Alabama, and the State of Washington who acted in their official capacity when they created the Fabry Stakeholder's Working Group to regulate the interstate supply of Fabrazyme, a drug owned by the Federal Government under the provisions of the Bayh-Dole Act. 37 U.S.C. 18 – PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE § 200 (which ensures "that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.")

452. The Compact Clause (U.S. Constitution, Art. 1, § 10, Clause 3) provides that "No State shall, without the Consent of Congress, ... enter into Any Agreement or Compact with another State, or with a foreign Power."

453. The Compact Clause is directed to the formation of any combination tending to the increase of political power in the States, which may encroach upon or interfere with the supremacy of the United States or the sovereign powers reserved to the States.

454. The entity Defendants entered into an unlawful interstate compact by sending their representatives Dr. Abiose (University of Iowa), Dr. Warnock (University of Alabama at Birmingham), and Dr. Scott (University of Washington) to the Fabry

Stakeholders Working Group to ration the national supply of Fabrazyme to the in contravention to the Interstate Commerce Clause as well contravening Congressional mandate of the Bayh-Dole act preventing non-use and misuse of a federally funded invention.

455. The purpose of the FSWG compact was to regulate the United States' supply of Fabrazyme using a capricious rationing method instead of instituting the standard of care during a drug shortage which is medical triage.

456. The Congress never approved the FSWG mandates rationing the supply of Fabrazyme for the nation or the individual states.

457. Officers at the National Institutes of Health and the FDA are skilled at handling drug shortages at the federal level and authorized by the President to act in the event of national shortage of a drug, not a combination of States.

458. All of the individual States have had laws regulating the public health predating the formation of the Union which include state officials acting to triage patients.

459. The intent and effect of the compact evidenced in the FSWG letters is that "low dose" Fabrazyme would be substituted for full dose Fabrazyme throughout the U.S. including Pennsylvania contrary to all the State and Federal Formularies detailing the approved dose of Fabrazyme for treating Fabry disease.

460. Both the regulation of medical practice and the prohibition of marketing and use of misbranded drugs within the State of Pennsylvania (and the other plaintiff's states) are core police powers reserved to the States to provide for the public health and safety of their respective citizens.

461. The FSWG member States expanded their authority to interfere with the sovereignty of the various states and the United States to force citizens to take a non-FDA-approved, ineffective dose of Fabrazyme in lieu of the State-licensed prescriptions of full dose Fabrazyme, which were necessary to protect the health and safety of citizens.

462. In addition, the FDA also exercises sovereign power from Congress to prohibit the marketing and sale of misbranded drugs under the Food, Drugs, and Cosmetics Acts.

463. The National Institutes of Health exercises sovereign power in that it prohibits interstate research on human medical subject as well as misuse of the invention termed Fabrazyme under the Bayh-Dole Act.

464. The Congress is the sole authority that can regulate interstate commerce of pharmaceutical drugs including Fabrazyme and interstate medical research.

465. The FSWG and its mandates regulating the national supply of Fabrazyme are in violation of the interstate compact clause.

466. The continued medical effects are still being felt in the United States and the unethical research on the effects of low dose is still ongoing on the citizens of Pennsylvania, including Plaintiffs' MASULA and DEMKO and the residents of the other Plaintiffs' States.

467. The continuing acts and harms directly resulted from the violation of the Interstate Compact clause in that the FSWG acted as the jurisdictional authority for approving he shipment of low dose Fabrazyme into commerce without state or federal authorization as well as to the research the effects of low dose on reciepients including Plaintiffs' MASULA and DEMKO.

468. The plaintiffs and their States reasonably fear that the formation and ongoing existence of the FSWG constitute a continued threat to how future shortages are managed if the compact is not declared unconstitutional.

469. The FSWG still holds monopoly power through its members over the use and distribution of Fabrazyme in the United States, which is the only authorized enzyme replacement therapy allowed to be sold by a single manufacturer in the United States.

470. The FSWG has never disbanded and its physician members continue to actively dispense and research the medical effects of Fabrazyme (both normal and low dose) on U.S. citizens without having obtained informed consent from those that were forced to take low dose Fabrazyme.

471. FSWG letters contain *prima facie* evidence of an Interstate Compact without Congressional authorization in that they contain:

a. The signatures of State Board Certified medical doctors, signing the documents on behalf of their respective Institutions that are arms of the State of Iowa, State of Alabama, and the State of Washington with the intent that they be sent outside their respective States in which they are licensed, and

b. The FSWG letters both notice and command that the FSWG would mandatorily reduce the full dose of Fabrazyme across all of the U.S. States in response to a national emergency, and

c. A statement of authority of the signatories by their respective institutions.

472. The intent and effect of the agreement among the FSWG members was to reduce the dose of Fabrazyme to render it ineffective for treating Fabry Disease throughout the United States thereby in contravening the core police powers reserved to

the Individual States and the State of Pennsylvania.

473. The Supreme Court has Original Jurisdiction over the FSWG, its State authorized members and their State institutions in this dispute concerning the sovereign powers of the State of Pennsylvania as against the powers of the authorized arms of the State of Iowa, State of Alabama, and the State of Washington.

WHEREFORE, Plaintiffs request the following relief:

A) An order for the immediate cessation of collection of data on U.S. Fabry patients until the National Institutes of Health can review the protocols for ClinicalTrials.gov Identifier: NCT00196742.

B) An order that a conservatorship be placed over these data so that patients can be re-consented and for those agreeing, the unrestricted publication of the de-identified full clinical results that have been obtained from "low- dosing" Americans with Fabrazyme in fulfillment of Defendants' promise to monitor "low dose" effects and to promote the advancement of medical science on Fabry disease instead of concealment; and

C) Declaratory judgment that a Combination of arms of the Defendant States (University of Iowa, University of Alabama at Birmingham, and University of Washington) acting together to regulate the supply of a pharmaceutical drug in interstate commerce, and regulate access to a pharmaceutical invention funded with federal assistance, and continue ongoing research the subsequent effects is Unconstitutional.

D) Restitution to all State and the Federal treasuries monies for the monies it

spent for paying for low dose Fabrazyme predicated on this violation of the Interstate Commerce Clause.

JURY TRIAL DEMANDED

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. An order for the immediate cessation of collection of data on U.S. Fabry patients until the National Institutes of Health can review the protocols for ClinicalTrials.gov Identifier: NCT00196742.

b. An order that a conservatorship be placed over these data so that patients can be re-consented and for those agreeing, the unrestricted publication of the de-identified full clinical results that have been obtained from "low- dosing" Americans with Fabrazyme in fulfillment of Defendants' promise to monitor "low dose" effects and to promote the advancement of medical science on Fabry disease;

c. Certification of this action or common issues herein as a class action;

d. A determination of common issues and claims in a unitary, consolidated, or class-wide trial pursuant to Fed. R. Civ. P. 23 and/or Fed. R. Civ. P 42;

e. An award of compensatory damages to each injured class member in an amount deemed appropriate by the trier of fact;

f. An award of punitive damages for acts and omissions of Defendant found to be willful and wanton, outrageous, and made with wickedness and reckless indifference to Plaintiffs' lives, health and interests;

g. An award of compensatory, equitable and/or restitution damages according to proof and for all applicable damages, remedies, and relief under applicable federal and state statutes including medical monitoring;

h. An award of costs of suit; and

i. Any other and further legal and/or equitable relief to which Plaintiffs might be entitled at law or which this Court deems proper.

ORAL ARGUMENT REQUESTED
JURY TRIAL DEMANDED

For the Plaintiffs,

/s/ C. Allen Black, Jr.

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